Supreme Court, U.S.
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No. 01-

IN THE
Supreme Court of the United States

MYCOGEN PLANT SCIENCE, INC.
and AGRIGENETICS, INC.,

Petitioners,

v.

MONSANTO COMPANY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a finding of prosecution history estoppel completely bars the application of the doctrine of equivalents (the "complete bar")? This question is identical to one that this Court has already accepted for review in the case of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., et al.*, 234 F.3d 558 (Fed. Cir. 2000) (en banc), *cert. granted*, 121 S. Ct. 2519 (2001) (No. 00-1543).

2. Whether cancellation of an independent claim and amendment of a dependent claim formerly dependent thereon into independent form justifies imposition of *Festo*'s "complete bar" where the sole limitation in the dependent claim was never amended during patent prosecution? This second question need only be addressed in the event that this Court adopts the "complete bar" rule announced in *Festo*.

3. Whether, under 35 U.S.C. § 271(g) ("Section 271(g)"), a party is liable for infringement when that party sells a product made by a process claimed in a patent where the sale of the end-product occurs during the term of the patent but the process was performed prior to the issuance of the patent?

STATEMENT PURSUANT TO RULE 29.6

Petitioner Mycogen Plant Science, Inc. states that its parent corporations are Rofan Services Inc. and Centen Ag Inc which are in turn wholly-owned by The Dow Chemical Company. The Dow Chemical Company is a publicly traded company. Petitioner Agrigenetics, Inc. states that it is wholly owned by petitioner Mycogen Plant Science, Inc.

TABLE OF CONTENTS

	Page
Questions Presented	i
Statement Pursuant to Rule 29.6	ii
Table of Contents	iii
Table of Cited Authorities	v
Table of Appendices	ix
Opinions Below	1
Statement of Jurisdiction	1
Constitutional and Statutory Provisions Involved	2
Statement of the Case	3
1. The '831 Patent	6
2. Relevant Prosecution History	8
3. Mycogen's Allegations	10
4. Monsanto's Motions For Summary Judgment And The District Court's Decisions	11
5. The Federal Circuit's Decisions Below	13

Contents

	Page
Reasons for Granting the Writ	17
1. Certiorari Should Be Granted To Ensure Consistency In the Application Of The Law In The Event That This Court Rejects The "Complete Bar" Announced In *Festo*	17
2. Certiorari Should Be Granted, Even In The Event That This Court Is Inclined To Affirm *Festo*, Because Of The Federal Circuit's Unwarranted Extension Of The "Complete Bar" Rule In This Case	21
3. Certiorari Should Be Granted To Correct The Federal Circuit's Improper Interpretation Of 35 U.S.C. § 271(g), Which Substantially Deprives Holders Of Process Patents Of Property Rights As Defined By Congress	24
Conclusion	29

TABLE OF CITED AUTHORITIES

Page

Cases:

Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991) 19

Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553 (Fed. Cir. 1996) 13, 25, 26

Campbell v. St. Tammany's School Board, 121 S. Ct. 2518 (2001) 17

Collazo-Aponte v. United States, 121 S. Ct. 1996 (2001) 17

Connecticut National Bank v. Germain, 503 U.S. 249 (1992) 27

Eli Lilly and Co. v. American Cyanamid Co., 82 F.3d 1568 (1996) 24

Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) 27

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., et al., 234 F.3d 558 (Fed. Cir. 2000) (en banc), *cert. granted*, 121 S. Ct. 2519 (2001) (No. 00-1543) ..... *passim*

Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605 (1950) 3

Cited Authorities

	Page
Hartford Underwriters Insurance Company v. Union Planters Bank, N.A., 530 U.S. 1 (2000)	27
Honeywell International, Inc. v. Hamilton Sundstrand Corporation, 2001 WL 66348 (D. Del. 2001)	23
Hughes Aircraft Co. v. United States, 717 F.2d 1351 (Fed. Cir. 1983)	20
Immigration and Naturalization Service v. Chun, 121 S. Ct. 2582 (2001)	17
Keney v. New York, 388 U.S. 440 (1967)	17
Lampi, LLC v. American Power Products, Inc., 65 F. Supp. 2d 757 (N.D. Ill. 1999)	22
Lawrence v. Chater, 516 U.S. 163 (1996)	17
Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373 (Fed. Cir. 1999)	3
United States v. Johnson, 457 U.S. 537 (1984)	17
Wright v. Vinton Branch Bank, 300 U.S. 440 (1937)	28
Zalawadia v. Ashcroft, 121 S. Ct. 2581 (2001)	17

Cited Authorities

Page

United States Constitution:

Article 1, section 8, clause 8 2

Statutes:

28 U.S.C. § 1254(1) 1

28 U.S.C. § 1331 10

28 U.S.C. § 1338 10

28 U.S.C. § 1367 10

35 U.S.C. § 102(g) 13

35 U.S.C. § 103 13

35 U.S.C. § 154(a)(1) 27

35 U.S.C. § 154(a)(2) 27

35 U.S.C. § 271(a) 2

35 U.S.C. § 271(g) ..... *passim*

Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994) 24

Rule:

United States Supreme Court Rule 13(3) 1

Cited Authorities

Page

Other Authorities:

H.R. 4526, 98th Cong., 1st Sess. (1983) 28

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House Report No. 100-60, 100th Cong., 1st Sess. (1987) 28

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Robert L. Stern *et al.*, *Supreme Court Practice* ¶5.9 (1993 7th ed.) 17

Brief of Amici Curiae Chiron Corporation, Guilford Pharmaceuticals, Inc., and Xoma In Support Of Petition For Writ Of Certiorari, Case No. 00-1543 (filed May 9, 2001) 18

Brief of Amicus Curiae Celltech Group, PLC. In Support Of Petitioner, Case No. 00-1543 (filed August 31, 2001) 18

TABLE OF APPENDICES

Page

Appendix A — Opinion Of The United States Court Of Appeals For The Federal Circuit Dated And Decided August 14, 2001 ..... 1a

Appendix B — Opinion Of The United States Court Of Appeals For The Federal Circuit Dated And Decided May 30, 2001 ..... 13a

Appendix C — Judgment Of The United States District Court For The Southern District Of California Dated, Entered And Filed November 15, 1999 ... 39a

Appendix D — Order Of The United States District Court For The Southern District Of California Lifting Stay And Granting Defendant's Motion For Summary Judgment Dated And Filed November 10, 1999 ..... 40a

Appendix E — Order Of The United States District Court For The Southern District Of California Re Motions For Summary Judgment Dated And Filed August 15, 1996 ..... 91a

Appendix F — Order Of The United States District Court For The Southern District Of California Denying Mycogen's Motion For Reconsideration Dated And Filed April 8, 1996 ..... 98a

Appendix G — Order Of The United States District Court For The Southern District Of California Dated December 26, 1995 And Filed January 2, 1996 ..... 100a

Appendices

Page

Appendix H — Order Of The United States District Court For The Southern District Of California Denying Motion For Reconsideration And Application To Certify For Interlocutory Appeal Dated December 4, 1995 And Filed December 5, 1995 ..... 104a

Appendix I — Order Of The United States District Court For The Southern District Of California Ruling In Part On Defendant's Summary Judgment And Ordering Further Briefing On Issue Of Prosecution History Estoppel Dated And Filed September 22, 1995 ..... 109a

Petitioners Mycogen Plant Science, Inc. and Agrigenetics, Inc. (referred to herein collectively as "Mycogen") hereby petition for a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The Federal Circuit's opinion reversing in part and affirming in part the judgment of the United States District Court for the Southern District of California is reported at *Mycogen Plant Sciences, Inc. v. Monsanto Co.*, 252 F.3d 1306 (Fed. Cir. 2001), and reproduced in the Appendix at 13a. The Federal Circuit's decision denying Mycogen's petition for rehearing on the issue of prosecution history estoppel is reported at *Mycogen Plant Sciences, Inc. v. Monsanto Co.*, 261 F.3d 1345 (Fed. Cir. 2001) and is reproduced in the Appendix at 1a. The District Court's opinions pertinent to the issues framed by the questions presented herein were issued on September 22, 1995, January 2, 1996 and November 10, 1999 and are not reported. They are reproduced in the Appendix at 109a, 100a and 40a respectively.

STATEMENT OF JURISDICTION

The United States Court of Appeals for the Federal Circuit issued its decision affirming the District Court judgment with respect to the issues raised in this petition on May 30, 2001 and, on August 14, 2001, denied a timely filed petition for rehearing by Mycogen. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1); *see also* S. Ct. Rule 13(3).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article 1, section 8, clause 8 of the Constitution provides:

> Congress shall have the power . . . to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their Respective Writings and Discoveries.

35 U.S.C. § 271(a) provides:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

35 U.S.C. § 271(g) provides:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process

will, for purposes of this title, not be considered to be so made after —

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

STATEMENT OF THE CASE

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., et al.*, 234 F.3d 558 (Fed. Cir. 2000) (en banc), the Federal Circuit, in a sharply divided en banc decision, held that any amendment that narrows a patent claim and is related to a statutory requirement for patentability gives rise to a prosecution history estoppel that completely bars the application of the doctrine of equivalents.[1] The *Festo* decision represents a drastic change in United States patent law, the sweeping consequences of which are now being felt by patent holders attempting to protect their inventions from unscrupulous copyists. This Court granted certiorari in June 2001 to review two questions presented by *Festo*: (1) Whether every claim-narrowing amendment designed to comply with any provision of the Patent Act — including those provisions not related to prior art — automatically creates prosecution history estoppel regardless of the reasons for the amendment;

1. The doctrine of equivalents prevents an accused infringer from avoiding liability for infringement by changing only minor or insubstantial details of a claimed invention while retaining the invention's essential identity. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). Prosecution history estoppel, on the other hand, is a doctrine that precludes a patentee from obtaining under the doctrine of equivalents coverage of subject matter that has been relinquished during the prosecution of its patent application. *See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376 (Fed. Cir. 1999).

and (2) Whether the finding of prosecution history estoppel completely bars the application of the doctrine of equivalents. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., et al.*, 121 S. Ct. 2519 (2001).

The first question this petition presents is identical to the second question presented in *Festo* — whether a finding of prosecution history estoppel completely bars the application of the doctrine of equivalents, thereby allowing one who makes insubstantial changes to a patented product to avoid infringement liability. In this case, the Federal Circuit applied *Festo* and held that prosecution history estoppel completely barred Mycogen from relying upon the doctrine of equivalents to establish that a gene developed by Monsanto infringed product claims contained in Mycogen's U.S. Patent No. 5,380,831 (the "'831 Patent"). Thus, to the extent that the "complete bar" announced in *Festo* is overturned, this case should be remanded to the Federal Circuit for further consideration. As discussed below, the facts of this case show the devastating impact that *Festo* has on the protection of patent rights in the field of biotechnology. As applied here, *Festo* deprives Mycogen of any infringement claim where the accused product is anything but an identical copy of the nucleotide sequence set out in Figure 1 of the '831 Patent.

The second question presented in this petition relates to the proper application of the "complete bar" announced in *Festo* to the extent that this Court otherwise adopts the rule. The Federal Circuit held in *Festo* that "an amendment that narrows the scope of a claim for any reason related to the statutory requirements of a patent will give rise to prosecution history estoppel with respect to the amended claim element." *See Festo*, 234 F.3d at 563. In this case, the Federal Circuit further interpreted *Festo* to hold that

> cancellation of a claim and replacement with another claim having an added limitation ha[s] the effect of narrowing the scope of the original claim and therefore should be treated as a claim amendment that create[s] a total bar to the doctrine of equivalents with respect to the limitation that was in effect added to the original claim.

See Appendix A at 9a-10a. On this basis, the Federal Circuit held that Mycogen was completely barred from relying on the doctrine of equivalents to prove infringement of the product claims of the '831 Patent even though the limitations of those claims alleged to be met by equivalents were contained in dependent claims filed as part of Mycogen's initial patent application and were never narrowed during the lengthy prosecution of the '831 Patent. *See* Appendix A at 11a-12a. This extension of the "complete bar" announced in *Festo* is unwarranted and substantially erodes the doctrine of equivalents as it survived *Festo*.

The third question presented relates to the Federal Circuit's restrictive interpretation of 35 U.S.C. § 271(g), which was enacted in 1988 as part of the Process Patent Amendment Act to broaden the protections afforded to holders of process patents. In particular, the Federal Circuit held that Section 271(g) does not impose liability for selling, using or importing products made by a patented process during the term of that patent unless the process also was performed during the patent's term. *See* Appendix B at 35a. This interpretation of Section 271(g) is contrary to the plain language of the statute and its legislative history, and deprives process patent holders of infringement claims based upon sales made during the patent term of products made by the patented process.

1. The '831 Patent

The '831 Patent contains both process and product claims. The process claims teach how to analyze and modify genes that encode for a pesticidal protein produced by the soil bacterium Bacillus thurigiensis (*Bt*) so that, when the gene is incorporated into a plant's DNA, the plant will produce the protein at high enough levels to protect the plant from insects. The product claims cover the sequence for two such genes.

Bt pesticidal protein is capable of killing certain crop-destroying insects but is not harmful to humans, animals, or beneficial insects such as bees and ladybugs. For many years, farmers have used *Bt* proteins to protect their crops, including potato, corn, and cotton plants. Traditionally, the *Bt* bacterium and *Bt* crystal protein were applied to crops externally through spraying. That technique is not always effective because some insects tunnel into plants soon after they hatch, or stay on the underside of leaves, and the spray does not reach them. Accordingly, scientists sought to create genetically-modified plants that produced their own *Bt* protein.

Scientists found that inserting "native" — meaning unmodified — *Bt* genes into plant cells resulted in plants that produced (*i.e.*, "expressed") *Bt* protein at levels too low to protect them from insects. The '831 Patent's process claims (claims 1-12) teach persons skilled in the art of plant genetics how to solve this problem by analyzing and modifying *Bt* genes to make them more compatible with a plant's own DNA.[2] The '831 Patent's product claims (claims 13 and 14)

2. The specific elements of the '831 Patent's process claims are not at issue in this petition. The only question presented in this petition that relates to these process claims is question three, which concerns the proper interpretation of 35 U.S.C. § 271(g). However, (Cont'd)

cover synthetic *Bt* genes designed by Mycogen's inventors through the claimed processes. The sequence for these genes is depicted in Figure 1 of the '831 Patent. Claim 13 covers a gene comprising nucleotides 1 through 1,793 of that sequence and claim 14 covers a gene comprising nucleotides 1 through 1,833 of that sequence. In order to understand how these genes differ from "native" *Bt* genes, it is necessary to detour briefly into the subject of molecular biology.

Genes are made up of DNA. Each strand of the DNA molecule comprises a sequence constructed of four chemical building blocks called "bases": adenine ("A"), cytosine ("C"), thymine ("T"), and guanine ("G"). These bases are held together by a sugar-phosphate backbone arranged like teeth on a zipper. One tooth of the zipper, or base-sugar-phosphate unit, is known as a "nucleotide." The order of the nucleotides is commonly referred to as the sequence of the DNA.

In a cell, the DNA in genes serves as the template for making complementary nucleotide strands of RNA. The cellular machinery then uses RNA to produce proteins. Nucleotide triplets, called "codons," instruct a cell to select certain amino acids that, in turn, are the building blocks of proteins. The codon sequence dictates the order in which amino acids are assembled to make a particular protein.

There are sixty-four possible condon triplets combinations of the four DNA bases. There are, however, only twenty different amino acids and eighteen of those twenty can be specified by more than one codon. Codons that specify the same amino acid are called "redundant."

(Cont'd)
in the case below, Monsanto conceded, for purposes of its motions addressing the proper interpretation of Section 271(g), that it practiced the steps of the processes claimed in the '831 Patent but did so before issuance of that patent.

As a result of redundant codons, two very different series of codons will encode for the same amino acid sequence and may be used to express the same protein.

The codons for a particular amino acid do not occur with equal frequency in organisms. Instead, categories of plants or animals have different preferences for the redundant codons that specify a particular amino acid. Organisms in defined categories, for instance, dicot plants (*e.g.*, potato, tomato, tobacco and cotton), monocot plants (*e.g.*, corn) and the native *Bt* bacteria, have common codon frequency distributions that can be calculated by counting codons in a gene.

The genes claimed in the '831 Patent differ from "native" *Bt* genes in that, while both the claimed genes and the "native" *Bt* genes encode for the *Bt* pesticidal protein, the claimed genes have been modified to utilize codons that are preferred by plants. The modified genes are thus more "plant-like" than the native *Bt* gene. When these modified genes are incorporated into a plant's DNA, the resulting plant "expresses" the *Bt* pesticidal protein at levels high enough to confer insect resistant properties.

2. Relevant Prosecution History

The prosecution history leading to the issuance of the '831 Patent's product claims, claims 13 and 14, is complex and is summarized here only briefly.

Mycogen's initial patent application, filed September 8, 1988, includes claims to specific gene sequences that ultimately issued as claims 13 and 14 of the '831 Patent. In that application, Mycogen sought approval for a broad independent product claim, claim 1, that recited "[a] synthetic gene sequence designed to be more highly expressed in plants encoding an insecticidal protein which is functionally equivalent to a native insecticidal protein of Bt." Rather than

pursuing additional independent claims covering the genes at issue in this case, Mycogen included limitations specifying the sequences of those genes in dependent claims 3 and 4, that depended from independent claim 1. Claim 3 and 4, as originally filed, recited:

> 3. A synthetic gene of claim 1 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1793.
>
> 4. A synthetic gene of claim 1 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1833.

During the prosecution of the '831 Patent, the Patent Examiner rejected claim 1 and several other independent claims proposed by Mycogen. As Mycogen proposed each new independent claim, it also amended claims 3 and 4 to depend from the new, independent claim.

Towards the end of the prosecution of the '831 Patent, the Patent Examiner indicated that, although the independent claim from which claims 3 and 4 depended at the time (claim 53) would be rejected, claims 3 and 4 would be allowable if rewritten in independent form. Mycogen agreed to this proposal, cancelled independent claim 53 without prejudice,[3] and rewrote claims 3 and 4, in accordance with the Examiner's proposed language, as follows:

> 3. A synthetic gene comprising the DNA sequence presented in Fig. 1, spanning nucleotides 1 through 1793.
>
> 4. A synthetic gene comprising the DNA sequence presented in Fig. 1, spanning nucleotides 1 through 1833.

3. After the cancellation without prejudice, Mycogen filed a continuation application that contained claim 53.

These claims, which are in independent form, were renumbered by Patent and Trademark Office in accordance with standard practice and issued as claims 13 and 14 of the '831 Patent.

3. Mycogen's Allegations

Mycogen commenced this patent infringement action on May 19, 1995 in the United States District Court for the Southern District of California. Subject matter jurisdiction was founded on 28 U.S.C. § 1338, as well as 28 U.S.C. §§ 1331 and 1367. The complaint identifies Mycogen as the owner of the '831 Patent and Agrigenetics as the licensee with the exclusive right to recover for patent infringement. The complaint charges Monsanto with infringing, or inducing infringement of, the '831 Patent and includes four other claims under state law. Mycogen subsequently filed amended complaints, on August 27, 1995 and December 18, 1995, containing the same basic allegations.

Monsanto's infringement was alleged to include two categories of conduct: first, the "making of synthetic *Bacillus thuringiensis* genes for expression in plants and seeds" using the methods claimed in the '831 Patent; and second, the "manufacture, use and sale" of agricultural products, including without limitation cotton, cottonseed, corn, potatoes, Bollgard cotton line, and NewLeaf potato lines, in which genes, either made using the processes covered by the '831 Patent's process claims or covered by the '831 Patent's product claims, are incorporated or expressed. Mycogen sought a judgment of infringement, an injunction prohibiting further direct and indirect infringement, compensatory damages, increased damages for willful infringement, and attorney's fees.

4. Monsanto's Motions For Summary Judgment And The District Court's Decisions

On July 5, 1995, Monsanto moved for summary judgment on Mycogen's claims for patent infringement. With respect to Mycogen's allegations that Monsanto had infringed the '831 Patent's process claims, Monsanto conceded for purposes of the motion that, prior to the issuance of the '831 Patent in January 1995, it practiced the process claimed in Mycogen's patent. However, Monsanto asserted that it had not used that process since the issuance of the patent and, accordingly, could not be held liable for infringement under 35 U.S.C. § 271(g). Mycogen argued in response that Monsanto could be liable under Section 271(g) for selling products produced using the process claimed in the '831 Patent, even if the process was performed before issuance of the patent, so long as the resulting products were used or sold during the patent's term.

With respect to the '831 Patent's product claims, Monsanto argued in its July 5, 1995 motion that a modified *Bt* gene used by Monsanto for insect resistant plants did not literally infringe Mycogen's patent because the Monsanto gene does not include the same nucleotide sequence specified in Figure 1 of the '831 Patent. Rather, because Monsanto used some different nucleotides to create the same amino acid sequence, approximately 19% of the nucleotides in Monsanto's gene differed from those comprising the gene sequence claimed in the '831 Patent. Monsanto also argued that Mycogen was estopped from asserting that the Monsanto gene infringed the '831 Patent under the doctrine of equivalents because of alleged prosecution history estoppel.

On September 22, 1995, the District Court granted in part and denied in part Monsanto's July 5, 1995 motion for summary judgment. *See* Appendix I at 109a. The District

Court held that Monsanto could not be held liable for infringement of process claims under Section 271(g) based on sales of the product of a process during the term of the '831 Patent where the patented process had only been performed before the patent issued. The court, however, found that issues related to Monsanto's practicing of the claimed processes after the '831 Patent issued were not ripe to be resolved as a matter of law.[4]

With respect to Mycogen's product claims, the District Court noted that there could be no literal infringement because of the differences between the two genes. As for infringement under the doctrine of equivalents, the District Court held that further discovery and expert opinion were necessary to create a record for adjudicating whether differences between the claimed genes and Monsanto's allegedly infringing gene are insubstantial. The District Court requested additional briefing on Monsanto's argument that prosecution history estoppel, in any event, barred Mycogen from invoking the doctrine of equivalents.

After further briefing, on January 2, 1996, the District Court held that Mycogen was estopped from raising the doctrine of equivalents in claiming infringement of the product claims in the '831 Patent. *See* Appendix G at 100a. The District Court focused on Mycogen's cancellation during the prosecution of the '831 Patent of dependent claims 2, 5 and 6. The District Court found that, on the basis of this history, a reasonable competitor would conclude that Mycogen intended to cancel all claims at least as broad as dependent claims 2, 5 and 6. Moreover, the District Court

4. On December 5, 1995, the District Court denied Mycogen's motion for reconsideration of the court's interpretation of Section 271(g) and also denied Mycogen's request to certify the issue of the proper interpretation of Section 271(g) for interlocutory appeal. *See* Appendix H at 104a.

found that these cancelled claims would not cover Monsanto's allegedly infringing gene. Thus, the District Court concluded that Mycogen was estopped from arguing that the doctrine of equivalents brought Monsanto's gene within the scope of the '831 Patent's product claims.[5]

On March 30, 1998, Monsanto moved for summary judgment on the grounds that the process claims in the '831 Patent are invalid under 35 U.S.C. §§ 102(g) and 103. Monsanto's motion relied in part on the purported collateral estoppel effects of a jury verdict rendered on February 5, 1998 in separate litigation between Mycogen and Monsanto related to two patents descended from the '831 Patent. On November 10, 1999, the District Court granted Monsanto's motion and dismissed Mycogen's complaint. *See* Appendix D at 40a.

5. The Federal Circuit's Decisions Below

Mycogen presented five questions to the Federal Circuit, only two of which relate to the subject matter of this petition. The questions related to this petition were: (1) Did the District Court err when it held, under Section 271(g) that products alleged to contain a gene made by the method claimed in the '831 Patent did not infringe the process claims as a matter of law where Monsanto performed the steps covering the

5. On April 8, 1996, the District Court denied a motion by Mycogen for reconsideration of the court's rulings with respect to the interpretation of Section 271(g) and the applicability of prosecution history estoppel. *See* Appendix F at 98a. The same day, the Federal Circuit issued a decision in the case of *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996), discussed below. Mycogen then moved for summary judgment in light of the Federal Circuit's interpretation of Section 271(g) in *Bio-Technology*. The District Court denied that motion on August 15, 1996. *See* Appendix E at 91a.

process for making the gene before the patent claims issued, and sold the products in the United States after issuance of the '831 Patent; and (2) Did the District Court err when it held that Monsanto's genes were outside the range of equivalents for the '831 Patent's product claims based on a limitation contained in dependent claims that were cancelled without prejudice during the prosecution, and without examining *de novo* the scope of any estoppel or the prior art. The remaining three questions presented related to the District Court's entry of summary judgment in favor of Monsanto on the issue of patent invalidity.

On May 30, 2001, the Federal Circuit issued an order affirming in part and reversing in part the judgment of the District Court. *See* Appendix B at 13a. The Federal Circuit held that the District Court improperly resolved disputed questions of material fact on the issue of patent invalidity and reversed the District Court to that extent.

The Federal Circuit, however, affirmed the District Court's ruling on the interpretation of Section 271(g) and its ruling that prosecution history estoppel bars Mycogen from establishing Monsanto's liability under the doctrine of equivalents. With respect to Section 271(g), the Federal Circuit held that liability under Section 271(g) for selling or using products "made by a process patented in the United States," requires that the patent be issued and in force at the time that the process is practiced as well as when the product is sold. *See* Appendix B at 35a. Accordingly, the Federal Circuit sustained the District Court's summary judgment ruling that Monsanto did not infringe Mycogen's process claims based on any process it performed before the patent issued.

With respect to prosecution history estoppel, the Federal Circuit had not issued its en banc decision in *Festo* when

Mycogen's appeal was briefed and argued. Mycogen thus argued, under pre-*Festo* law, that the District Court erred in holding that prosecution history estoppel barred Mycogen from asserting infringement of its product claims under the doctrine of equivalents. In particular, Mycogen argued that the District Court failed to properly evaluate the scope of any estoppel arising from Mycogen's cancellation of dependent claims 2, 5 and 6 in light of what actually was surrendered. Mycogen contended that a reasonable competitor would have concluded that Mycogen actually surrendered nothing by canceling dependent claims 2, 5, and 6 for several reasons, including: the limitations of dependent claims 2, 5, and 6 were never added to any of the independent claims from which claims 3 and 4 depended during prosecution and thus were never incorporated into dependent claims 3 and 4; claims 3 and 4 never depended from any of claims 2, 5, or 6; claims 2, 5, and 6 were cancelled without prejudice; and Mycogen pursued an even *broader* claim, independent claim 53, in the same application. Moreover, while independent claim 53 was later rejected by the Patent Examiner based on prior art and was cancelled without prejudice, Mycogen argued that the District Court failed to consider the proper scope of any estoppel resulting from that cancellation. Claims 3 and 4 had depended from claim 53, and the Patent Examiner allowed them despite a prior art objection to independent claim 53. Mycogen maintained, in light of the prior art at issue, that any estoppel arising from the cancellation of claim 53 should not prevent Mycogen from relying upon the doctrine of equivalents to prove that Monsanto's gene infringed the product claims that issued in the '831 Patent.

On November 29, 2000, the Federal Circuit issued its en banc decision in *Festo* and radically altered the law applicable to prosecution history estoppel and the doctrine of equivalents. In its May 30, 2001 opinion in this case, the

Federal Circuit rejected all of Mycogen's arguments regarding the appropriate scope of any prosecution history estoppel applicable to the '831 Patent's product claims. The Federal Circuit applied the "complete bar" announced in *Festo* and held that no range of equivalents was available to Mycogen to protect patented products from copyists. *See* Appendix B at 38a.

On June 13, 2001, Mycogen filed a petition for rehearing on the issue of prosecution history estoppel addressing, for the first time, the Federal Circuit's decision in *Festo*. Mycogen argued that the Federal Circuit erred when it ruled that *Festo's* complete bar eliminated all need to analyze Mycogen's product claims under the doctrine of equivalents even though those claims were never subject to any narrowing amendment during the patent's prosecution.

On August 14, 2001, the Federal Circuit denied Mycogen's petition. *See* Appendix A at 1a. The Federal Circuit interpreted *Festo* to hold that

> cancellation of a claim and replacement with another claim having an added limitation ha[s] the effect of narrowing the scope of the original claim and therefore should be treated as a claim amendment that create[s] a total bar to the doctrine of equivalents with respect to the limitation that was in effect added to the original claim.

See Appendix A at 9a-10a. On this basis, the Federal Circuit concluded that, because Mycogen cancelled broader claims prior to the allowance of independent claims 13 and 14, Mycogen was completely barred from relying upon the doctrine of equivalents. The Federal Circuit gave no weight to the fact that the limitations of claims 13 and 14 alleged to be infringed by the doctrine of equivalents were present in

dependent claims 3 and 4 of Mycogen's initial patent application and were never narrowed during the patent's prosecution.

REASONS FOR GRANTING THE WRIT

1. Certiorari Should Be Granted To Ensure Consistency In the Application Of The Law In The Event That This Court Rejects The "Complete Bar" Announced In *Festo*

As discussed above, the Federal Circuit in this case held based on *Festo* that prosecution history estoppel completely barred Mycogen from relying upon the doctrine of equivalents to establish infringement by Monsanto of the product claims of the '831 Patent. To the extent that this Court reverses or modifies *Festo*, this case should be remanded to the Federal Circuit for proceedings consistent therewith. *See Immigration and Naturalization Service v. Chun*, 121 S. Ct. 2582 (2001) (petition for certiorari granted, judgment vacated and case remanded following the decision in a related case); *Zalawadia v. Ashcroft*, 121 S. Ct. 2581 (2001) (same); *Campbell v. St. Tammany's School Board*, 121 S. Ct. 2518 (2001) (same); *Collazo-Aponte v. United States*, 121 S. Ct. 1996 (2001) (same); *see also* Robert L. Stern *et al.*, *Supreme Court Practice* ¶5.9 (1993 7th ed.) ([A petition for certiorari] may be held until a decision is reached by the Court in a pending case raising identical or similar issues (*citing Keney v. New York*, 388 U.S. 440 (1967)). To deny certiorari in this case would deny Mycogen equal treatment under the law in the event that the "complete bar" announced in *Festo* is overturned. *See Lawrence v. Chater*, 516 U.S. 163, 167 (1996) (order granting certiorari, vacating the judgment and remanding in cases related to matter accepted for full briefing alleviates the "'[p]otential for unequal treatment' that is inherent in our inability to grant plenary review of all pending cases raising similar issues." (*quoting United States v. Johnson*, 457 U.S. 537, 555 n.16 (1984))).

Because this case involves product claims covering gene sequences, full briefing would allow this Court to evaluate *Festo's* impact on a significant, developing area of new technology. In his opinion concurring in part and dissenting in part from the *Festo* en banc ruling Judge Michel emphasized the "magnitude of the effects that will ensue from [the majority's] new rule" that a finding of prosecution history estoppel completely bars the application of the doctrine of equivalents. 234 F.3d at 617. Judge Michel warned that "[c]opyists will be able to apply [*Festo*] . . . to avoid liability in many, if not all, areas of technology." *Id.* (Michel, J., dissenting in part). He identified biotechnology as "one critical field of technology that may be particularly harmed by [*Festo*]" and expressed concern that "[c]ompletely barring resort to the doctrine of equivalents for amended claim limitations may drastically limit the scope of protection for biotechnology patents, such as those claiming a protein molecule." *Id.*

Judge Lourie, in a concurring opinion, rejected Judge Michel's concerns regarding the impact of *Festo* on the biotechnology industry as "largely theoretical." *Id.* at 597 (Lourie, J., concurring). Theory, however, has become reality in this case. Here, the Court has a concrete example of Judge Michel's accurate prophecy that *Festo* will undermine patent protection in the field of biotechnology. [6]

Taking as an example a patent claiming a protein, Judge Michel explained how *Festo* would inappropriately constrict the availability of the doctrine of equivalents to protect a patentholder's property rights

6. The impact of *Festo* upon the protection of biotechnology patents is discussed in two amicus briefs filed with this Court in support of the petitioner in the *Festo* case. *See* Brief of Amici Curiae Chiron Corporation, Guilford Pharmaceuticals, Inc., and Xoma In Support Of Petition For Writ Of Certiorari, Case No. 00-1543 (filed May 9, 2001); Brief of Amicus Curiae Celltech Group, Plc. In Support Of Petitioner, Case No. 00-1543 (filed August 31, 2001).

> A protein molecule can only be claimed as the complete and specific sequence of amino acids comprising the protein. *See* 37 C.F.R. § 1.821 (2000). The particular amino acids that comprise a protein chain are frequently interchangeable with other amino acids without changing the protein or its functions. As our court noted with respect to a patent claiming the protein erythropoietin, "over 3,600 different [protein] analogs can be made by substituting [interchangeable acids] at only a single amino acid position, and over a million different analogs can be made by substituting three amino acids." *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213, 18 U.S.P.Q.2d 1016, 1026 (Fed. Cir. 1991). Many such analogs are functionally identical to the claimed protein. Thus, a competitor seeking to make, use, or sell a protein that is protected by a patent containing an amended claim limitation will only have to substitute at a particular location in the chain an interchangeable amino acid for the particular amino acid recited in the patent claim as occupying that location. It appears that, in order to thwart such copying, a patent applicant would have to disclose and claim every single analog that is functionally equivalent to the claimed protein. Considering the vast number of specific amino acid sequences that an applicant would be forced to disclose and claim in order to secure meaningful protection for his invention, I feel the majority's rule puts an impossible burden on both the applicant and the PTO.

See Festo, 234 F.3d at 617 (Michel, J., dissenting in part).

The '831 Patent claims genes, not proteins, but the concerns are identical. Just as the interchangeability of amino acids provides copyists a "road map" to undermine patents claiming proteins, the redundancy of codons provides copyists a fail-safe method to avoid literal infringement of patents claiming genes by making insubstantial changes to the claimed genetic sequence.[7]

Because of redundant codons, if the holder of a patent claiming a specific gene sequence is completely barred under *Festo* from relying upon the doctrine of equivalents, the patent becomes ineffective to protect the underlying invention. A would-be copyist could escape infringement by substituting a codon in the claimed sequence with another that codes interchangeably for the same amino acid. Before *Festo*, a court would have considered whether the prosecution history reflected a surrender of claim coverage for a product with trivial changes of this nature and, if not, would have considered whether the accused product infringed under the doctrine of equivalents. *See, e.g., Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1363 (Fed. Cir. 1983). After *Festo*, however, a finding of prosecution history estoppel cuts off this analysis and would require a judgment of non-infringement as a matter of law in favor of the copyist. *See Festo*, 234 F.3d at 563.

Mycogen now faces that scenario. By changing a *single* nucleotide in the 1793 or 1833 nucleotide genes claimed in the '831 Patent, a copyist could produce a gene that encodes the identical protein but would avoid literal infringement of the '831 Patent's product claims. *Festo*, as applied here by

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7. As explained above, amino acids are encoded by combinations of three nucleotides, referred to as "codons." There are sixty-four different codons but only twenty different amino acids, eighteen of which can be specified by more than one codon. Codons that specify the same amino acid are called "redundant."

the Federal Circuit, precludes Mycogen from invoking the doctrine of equivalents to prove infringement no matter how insubstantial a change was made to the gene sequence. While Monsanto's accused product has more than a one-nucleotide difference from Mycogen's claimed invention, that was irrelevant to the Federal Circuit's analysis. Thus, the Federal Circuit's holding that Mycogen is estopped from relying on the doctrine of equivalents did not *limit* the protection afforded Mycogen's patent claims; it *eliminated* any meaningful protection for Mycogen's invention.

2. Certiorari Should Be Granted, Even In The Event That This Court Is Inclined To Affirm *Festo*, Because Of The Federal Circuit's Unwarranted Extension Of The "Complete Bar" Rule In This Case

The Federal Circuit held in *Festo* that "an amendment that narrows the scope of a claim for any reason related to the statutory requirements of a patent will give rise to prosecution history estoppel with respect to the amended claim element." *See Festo*, 234 F.3d at 563. *Festo* established a four part analysis for determining whether amendment-based estoppel applies: *First*, the court must determine which claim limitations are alleged to be met by equivalents; *Second*, the court must determine whether those limitations were amended during prosecution of the patent; *Third*, the court must consider whether the amendments narrowed the literal scope of the claim; and *Fourth*, the court must determine whether the patentee can prove that the amendment was unrelated to any statutory requirement for patentability. If the court finds that a claim was narrowed by amendment in order to satisfy a statutory requirement for patentability, then prosecution history estoppel applies and no range of equivalents is available with respect to the amended claim limitations. *See id.* at 586.

The Federal Circuit did not apply *Festo's* four-part test in this case. Instead, it applied *Festo's* "complete bar" to Mycogen's product claims based on the theory that

> cancellation of a claim and replacement with another claim having an added limitation ha[s] the effect of narrowing the scope of the original claim and therefore should be treated as a claim amendment that create[s] a total bar to the doctrine of equivalents with respect to the limitation that was in effect added to the original claim.

See Appendix A at 9a-10a. Assuming that rule could be correctly applied in some circumstances, its announcement and application here greatly extended *Festo* and contracted the scope of the doctrine of equivalents.

As discussed above, Mycogen's initial patent application included the genes covered by claims 13 and 14 of the '831 Patent. Rather than pursuing additional independent claims covering the gene sequences, Mycogen included limitations related to the sequences of the genes in two dependent claims, claims 3 and 4. An "independent claim" is a claim that does not refer to any other claim of the patent and is read separately to determine its scope. *Lampi, LLC v. American Power Products, Inc.*, 65 F. Supp. 2d 757, 761 (N.D. Ill. 1999). A "dependent" claim, in contrast, refers to at least one other claim in the patent, includes all of the limitations of the claim to which it refers and specifies further limitations on that claim. *Id.* In the case of claims 3 and 4, the limitations specifying the sequences for the genes at issue initially were "further limitations" on claim 1, an independent claim. During the course of the prosecution of the '831 Patent, claims 3 and 4 were amended several times to depend from different independent claims. However, the limitations alleged to be met by equivalents in this case — those

specifying the sequences for the genes covered by Mycogen's product claims — were never amended by Mycogen. Rather, towards the end of the prosecution of the '831 Patent, the Patent Examiner indicated that dependent claims 3 and 4 would be allowable if rewritten in independent form. Mycogen did so, and the rewritten claims issued as claims 13 and 14 of the '831 Patent.

Under these circumstances, claims 13 and 14 should not be considered, in any sense, "replacement claims" that added a limitation to the original independent claim. Rather, the Federal Circuit should have, at minimum, treated claims 13 and 14 as amended versions of claims 3 and 4 and applied *Festo*'s four part test on that basis. Following *Festo*, a court would first determine "which claim limitations are alleged to be met by equivalents." *See Festo*, 234 F.3d at 586. The only answer to that question here is the limitations of claims 13 and 14 that specify the nucleotide sequences for the genes claimed in the '831 Patent. A court applying *Festo* would then analyze "whether those limitations were amended during prosecution of the patent." The record shows that the limitations of claims 3 and 4 were never amended. The limitations alleged to be met by equivalents in this case were present in claims 3 and 4 at the beginning of the prosecution of the '831 Patent and were carried through to the issued claims 13 and 14 without being changed, let alone narrowed. Thus, even under the logic of *Festo*, there was no basis for applying the "complete bar" to Mycogen's product claims in this action.[8]

8. Indeed, this is precisely the type of analysis performed by a District Court interpreting *Festo* in *Honeywell International, Inc. v. Hamilton Sundstrand Corporation*, 2001 WL 66348, *6 (D. Del. 2001). In *Honeywell*, the District Court held that the "complete bar" announced in *Festo* did not apply where the patentee rewrote dependent claims into independent form in order to obtain allowance because the claim elements at issue were not amended in that process. *Id.*

The Federal Circuit's extension in this case of the already draconian "complete bar" to apply to the unamended claim limitations of Mycogen's patent claims should be reversed by this Court even if *Festo* is otherwise affirmed. At minimum, this Court should review and provide guidance to lower courts and to patent holders regarding the application of the "complete bar" announced in *Festo* to cases like this, where there has been no "claim-narrowing" amendment.

3. Certiorari Should Be Granted To Correct The Federal Circuit's Improper Interpretation Of 35 U.S.C. § 271(g), Which Substantially Deprives Holders Of Process Patents Of Property Rights As Defined By Congress

The Process Patent Amendments Act of 1988 was enacted to close a perceived loophole in the statutory scheme for protecting owners of United States process patents. *See Eli Lilly and Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1571 (1996). Prior to the enactment of the 1988 statute, a patentee holding a process patent could sue for infringement if others used the process in this country, but had no cause of action if such persons used the patented process abroad to manufacture products, and then imported, used, or sold the products in this country. *Id.* By enacting the Process Patent Amendments Act, the principal portion of which is codified as 35 U.S.C. § 271(g), Congress changed the law by making it an act of infringement to import into the United States, or to sell or use within the United States "a product which is made by a process patented in the United States ... if the importation, sale, or use of the product occurs during the term of such process patent." *Id.*[9] By that amendment Congress made the sale of a product produced by a process an act of infringement independent of practicing the process.

9. A provision concerning offers to sell was added to Section 271(g) by the Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809, 4988 (1994) (effective Jan. 1, 1996).

While the importation loophole may have motivated the amendment, the law enacted was not confined to that situation. The legislative history states that Section 271(g) was intended to "provide that issuance of a process patent includes the right to exclude others from using or selling in the U.S., *or* importing into the U.S. products made by that process." H.R. Conf. Rep. No. 100-576, Omnibus Trade and Competitiveness Act of 1988, 100th Cong. 2nd Sess. (1988) Pub. L. No. 100-418, 102 Stat. 1107, *reprinted in* 1988 U.S.C.C.A.N. 1547, 2118 (emphasis added).

This case presents the issue of whether, under Section 271(g), a party can be held liable for infringement for selling products made by a process claimed in a patent where the sales took place during the term of the patent but the process was performed under circumstances that did not give rise to infrigement liability. That question had been answered by the Federal Circuit's interpretation of Section 271(g) in the case of *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1560 (Fed. Cir. 1996), which considered whether Section 271(g) imposed infringer liability for the sale of a product during the term of a process patent where the defendant had performed the claimed process outside the United States and before the enactment of Section 271(g), and thus did not have any infringement liability. *Bio-Technology General Corp.*, 80 F.3d at 1560, 38 USPQ2d at 1326. The defendant contended that it could not be held liable for infringement because "it only constructed the plasmid [the product resulting from the patented process] once, in Israel in 1983, before the enactment of [Section] 271(g)" and liability for the subsequent sale of the product in the United States would improperly apply Section 271(g) retroactively. *Bio-Technology General Corp.*, 80 F.3d at 1560, 38 USPQ2d at 1326. The Federal Circuit held that the later sale constituted infringement under Section 271(g) without reference to when (or whether) the defendant had practiced the covered process.

The *Bio-Technology* Court emphasized that "[i]nfringement under [Section] 271(g) does not consist of the making of a product by a process patented in the United States; it is the importation, offer to sell, sale, or use of a product made by such process." *Id.* at 80 F.3d at 1560. Thus, the Federal Circuit determined that "[l]iability arises if 'the importation, sale, offer to sell, or use of the product occurs during the term of such process patent.'" *Id.* at 80 F.3d at 1560.[10]

In this case, however, the Federal Circuit held that it is not sufficient to impose liability under Section 271(g) that the "sale, offer to sell, or use of the product" occurs during the patent term. Rather, the Federal Circuit imposed an additional requirement to liability under Section 271(g): that the performance of the claimed process also occur during the patent term. *See* Appendix B at 35a. In so doing, the Federal Circuit adopted an interpretation of Section 271(g) that conflicts with the statutory language, with legislative history and with its own decision in the *Bio-Technology* case.

With respect to the statutory language, Section 271(g), as acknowledged in *Bio-Technology*, provides that liability should be imposed if "the importation, sale, offer to sell, or use of the product occurs during the term of such process patent." There is no requirement that the process also be performed during the patent term. A leading treatise on patent law thus concluded:

> Liability [under Section 271(g) arises if the defined acts (i.e., importing, selling, or using the product made by the patented process) occur in

10. On that basis, the Federal Circuit held in *Bio-Technology* that a party could be liable for making and importing into the United States a product made by a patented process even though the process had only been performed before the enactment of Section 271(g).

> the United States during the process patent's term. *It is immaterial that the infringer used the process before the patent issued* — or, indeed, before the [Patent Process Amendment Act] became effective (emphasis added).

See 5 Donald S. Chisum, *Chisum On Patents* § 16.02[6][d][i]. Where, as here, a statute is clear on its face, a Court should not depart from that plain meaning. *See Hartford Underwriters Insurance Company v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) ("when the statute's language is plain, the sole function of the courts — at least where the disposition required by the text is not absurd — is to enforce it according to its terms" (citations omitted)); *Connecticut National Bank v. Germain*, 503 U.S. 249, 253-254 (1992) ("We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there. When the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete'" (citations omitted)).

The Federal Circuit's interpretation of Section 271(g) in this case does not give effect to the Act taken as a whole. If a person may use a process pre-patent to produce a product that they later sell during the term of a patented process, and not have any infringement liability under Section 271(g), then the process patent holder does not receive the statutorily mandated "right to exclude others from using, offering for sale or selling throughout the United States, . . . products made by that process" for a period of 20 years. *See* 35 U.S.C. § 154(a)(1) and (2); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990).

Further, to the extent at all relevant, the legislative history of Section 271(g) also supports the imposition of liability irrespective of when the underlying process was performed.

In the early stages of this legislation, Congressman Kastenmeier introduced a bill that proposed an amendment in the following form:

> (e) Whoever without authority imports into or sells or uses within the United States a product which is made in another country by a process patented in the United States shall be liable as an infringer, if the product is made during the term of such process patent.

H.R. 4526, 98th Cong., 1st Sess. (1983). This version of the bill thus expressly provided that for there to be infringement liability, the product must have been "made during the term of such process patent." Congressman Kastenmaier's language was dropped in subsequent bills, however, and no similar language ever appeared in any bill later proposed or adopted (See House Report No. 100-60, 100th Cong., 1st Sess. (1987), Senate Report No. 100-83, 100th Cong. 1st Sess. (1987) and H.R. Conf. Rep. No.100-576, Omnibus Trade and Competitiveness Act of 1988, 100th Cong. 2nd Sess. (1988) *reprinted in* 9 Donald S. Chisum, *Chisum on Patents* App. 25-1). The omission of this language in the final bill is further evidence that Congress intended to impose liability for any commercial exploitation of products of a patented process, as the statute provides, so long as the "importation, sale, offer to sell, or use of the product occurs during the term of such process patent." *See Wright v. Vinton Branch Bank*, 300 U.S. 440, 463 n.8 (1937) ("where the meaning of legislation is doubtful or obscure, resort may be had in its interpretation . . . to comparison of successive drafts or amendments of the measure" (citations omitted)).

The Federal Circuit's interpretation of Section 271(g) in this case opens a loophole that should have been closed when Congress amended Section 271(g) in 1988. As the facts of this case show, competitors now may have the opportunity

to exploit the product of a process, free from infringement liability, during the term of the patent. That risk is particularly acute where, as here, the claimed process need only be practiced once and the resulting product can be commercialized for years to come. Whether the Federal Circuit erred in construing Section 271(g) to impose liability only when the process at issue is performed during the patent's term thus presents an important question of patent law that should be addressed by this Court.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED AND DECIDED AUGUST 14, 2001

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

00-1127

MYCOGEN PLANT SCIENCE, INC.
and AGRIGENETICS, INC.,

Plaintiffs-Appellants,

v.

MONSANTO COMPANY,

Defendant-Appellee.

* * *

Appealed from: United States District Court for the Southern District of California
Judge Napoleon A. Jones, Jr.

DECIDED: August 14, 2001

ON PETITION FOR REHEARING

Before CLEVENGER, BRYSON, and LINN, *Circuit Judges.*

BRYSON, *Circuit Judge.*

Appendix A

Based on the prosecution history of Mycogen's U.S. Patent No. 5,380,831 (the '831 patent), we held in our initial opinion in this case that Mycogen is not entitled to invoke the doctrine of equivalents with respect to claims 13 and 14 of the patent. 252 F.3d 1306, 1319-20, 58 USPQ2d 1891, 1901-02. In its petition for rehearing, Mycogen contends that we misunderstood the prosecution history of the '831 patent and, as a result, mistakenly held the doctrine of equivalents inapplicable to claims 13 and 14.

The prosecution history leading to the issuance of claims 13 and 14 of the '831 patent is complex. We did not describe it in detail in our initial opinion, but have done so here. Although Mycogen contends that the details of the prosecution history require a different analysis of the doctrine of equivalents issue, we are not persuaded that anything in the prosecution history to which Mycogen has called our attention justifies a different result from the one reached in our original opinion.

In brief summary, the prosecution history of claims 13 and 14 reveals that Mycogen first applied for claims providing broad coverage, and then subsequently engaged in a long prosecution negotiation with the Patent and Trademark Office ("PTO"). During the course of the prosecution, Mycogen narrowed the scope of its application through a series of increasingly narrow claims. The PTO, however, rejected all of those claims and ultimately proposed language that limited what became claims 13 and 14 to segments of a specific DNA sequence disclosed in the application. Mycogen agreed to the proposed language and agreed to cancel its broader related claims. It is that series of events, described in more detail

below, that provides the factual background for Mycogen's doctrine of equivalents argument.

Mycogen's application No. 07/242,482 (the '482 application), filed on September 9, 1988, included application claims 1, 3, and 4:

> 1. A synthetic gene designed to be highly expressed in plants comprising a DNA sequence encoding an insecticidal protein which is functionally equivalent to a native insecticidal protein of Bt.
>
> 3. A synthetic gene of claim 1 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1793.
>
> 4. A synthetic gene of claim 1 wherein said DNA sequence is that presented in Figure 1 spanning nucleotides 1 through 1833.

Those claims were rejected on a number of grounds. Claim 1 was rejected under the second paragraph of 35 U.S.C. § 112 as being indefinite, and all claims were rejected under the first paragraph of section 112 because the specification was enabling only for claims limited to dicot plant cells. The examiner observed that the disclosure was enabling only for the specific sequence shown in Figure 1, and that in view of the unpredictability of foreign gene expression, it did not appear that any functionally equivalent synthetic gene would be effective in any plant cell. Finally, the claims were rejected as obvious.

Appendix A

In response to arguments made by Mycogen, the examiner again concluded that the disclosure was enabling only for the specific sequence shown in Figure 1. The examiner further remarked that Mycogen had not provided evidence that the sequence of Figure 1 or any other sequence is highly expressed in plants and reiterated that, in light of the unpredictability of expression, even very similar genes might not express a protein that would be an effective toxin.

Following final rejection of the '482 application, Mycogen filed a continuation that became application No. 07/827,844 (the '844 application). In that application, claims 3 and 4 from the '482 application were amended to depend from new application claim 31, which was significantly narrower than '482 application claim 1. The change in dependency had the effect of narrowing the scope of claims 3 and 4. Claim 31 provided as follows:

> 31. A synthetic gene designed to be highly expressed in plants comprising a DNA sequence encoding a Bt insect toxic polypeptide which is functionally equivalent to a native insecticidal protein of Bt, having toxicity to a specific insect, and wherein said synthetic gene is designed by modifying a native Bt gene by at least one of a plurality of factors affecting Bt mRNA synthesis or degradation in plants selected from the group of factors consisting of (a) preferred codon usage, (b) A+T base content, (c) CG and TA doublet avoidance indices, (d) RNA destabilizing sequence, (e) translation initiation sequence, (f) plant polyadenylation signal, (g) RNA

degradation signal, (h) polymerase II termination sequence, (i) CUUCGG hairpin and (j) plant consensus split site.

The claims of the '844 application were rejected under the second paragraph of 35 U.S.C. § 112 for indefiniteness. In addition, claim 31 was rejected under the first paragraph of 35 U.S.C. § 112 on written description and enablement grounds. The examiner again noted that the disclosure was enabling only for the specific sequence shown in Figure 1 of the specification. Although the application recited a synthetic gene encoding a functional equivalent of any native Bt protein, the examiner pointed out that the applicants had shown only one Bt-derived synthetic gene, the sequence of which was shown in Figure 1. The examiner concluded that the applicants "have provided insufficient guidance to justify the breadth of the claims." The examiner reiterated that there must be a reasonable predictability that following the teaching of the disclosure will result in the claimed invention, and found no assurance that any of the claims recited any operable species. Although Mycogen had submitted declarations attempting to provide such assurance, the examiner found the declarations insufficient. In particular, the examiner found that the testing supporting the declarations did not support the broad claims because only one construct was tested, and the testing did not support claims 3 and 4 because the declaration did not refer to the construct of Figure 1. In addition, the examiner rejected claim 31 for obviousness.

In response to that office action, Mycogen amended the '844 application. It canceled claim 31, substituted new claim 35 in its place, and added claim 36. Claims 35 and 36, from which

Appendix A

claims 3 and 4 were made to depend, were narrower than claim 31. Once again, then, the amendment had the effect of narrowing the scope of claims 3 and 4. Also, independent claim 51 and dependent claim 52, which contained the Figure 1 limitations, were added. The new and modified claims provided as follows:

> 36. A synthetic gene designed to be highly expressed in plants comprising a DNA sequence encoding a Bt insecticidal protein, said synthetic gene having modified codons in a Bt coding region.
>
> 35. A synthetic gene of claim 36 wherein said DNA sequence is characterized by at least one of a plurality of factors selected from the group of factors consisting of: (a) utilization of plant preferred codon usage to within about 75% of the frequency of codon usage preferred by plants as in Table 1, (b) utilization of an A+T base content substantially equal to the A+T base content found in plant structural genes as in Table 1, (c) utilization of CG and TA doublet avoidance indices substantially equal to those of selected a host plant, (d) utilization of a plant translation initiation sequence, (e) elimination of plant polyadenylation signals comprising those having AATAAA, AATGAA, AATAAT, AATATT, GATAAA and AATAAG motifs, (f) elimination of polymerase II termination sequences, $CAN_{7-9}AGTNNAA$, (g) elimination of CUUCGG hairpins and (h) elimination of plant consensus splice sites, including 5'=AAG:GTAAGT and 3'=TTTT(Pu)TTT(Pu)T(Pu)T(Pu)T(Pu)TGCAG:C.

Appendix A

3. A synthetic gene of claim 35 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1793.

4. A synthetic gene of claim 35 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1833.

51. A synthetic gene designed to be highly expressed in plants comprising a DNA sequence encoding a Bt insecticidal protein, said DNA sequence being that presented in Figure 1, spanning nucleotides 1 through 1793.

52. A synthetic gene of claim 51 wherein said DNA sequence spans nucleotides 1 through 1833.

All of those claims were rejected under the first paragraph of 35 U.S.C. § 112 on written description and enablement grounds. Claims 3, 4, and 35 were also rejected under the second paragraph of 35 U.S.C. § 112 for indefiniteness. In addition, the examiner rejected claims 3, 4, 51, and 52 under the fourth paragraph of 35 U.S.C. § 112 for being in improper dependent form or failing to further limit the subject matter of a previous claim. The examiner again found that the disclosure enabled only the Figure 1 sequence and found, in light of the unpredictable effect of changes in gene sequences, that even if the declarations offered by Mycogen clarified that the Figure 1 construct was tested and operable, that evidence would be helpful only if the claims were limited to the sequence set forth in Figure 1.

Appendix A

Following an interview, new claim 53 was added, and claims 3 and 4 were again amended, this time to make them depend from claim 53. The other pending claims were cancelled. The new claims provided as follows:

> 53. A synthetic Bt gene derived from a native Bt gene and expressible in plants at a level higher than the corresponding native Bt gene, wherein the DNA sequence of the native Bt gene has been modified in the synthetic gene to contain a frequency of codon usage that more closely resembles the frequency of codon usage of the plant in which it is to be expressed, and wherein the modified DNA sequence encodes substantially the same amino acid sequence as did the native Bt DNA sequence from which it was derived.
>
> 3. A synthetic gene of claim 53 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1793.
>
> 4. A synthetic gene of claim 53 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1833.

Claim 53 was then rejected under the second paragraph of section 112 as indefinite. Again, the examiner stated that there must be reasonable predictability that following the teaching of the disclosure will result in the claimed invention, and found that there was no assurance that the claimed invention was enabled for the scope recited. The examiner withdrew the prior rejection of claims 3 and 4 under the first

paragraph of section 112 in view of the amendments and arguments made, specifically the clarification that the construct tested as described in the submitted declarations was that of Figure 1. Finding the declarations persuasive with regard to claims 3 and 4 only, the examiner stated that it was "impossible to determine how much experimentation was required to obtain the one success exemplified." Accordingly, the examiner concluded that "the claims should be limited to the sequence shown in Figure 1 as disclosed in the Examples of the instant application." The examiner stated that claims 3 and 4 would be allowable if rewritten in independent form. Following another interview, Mycogen agreed to cancel the non-allowed claims and agreed to the examiner's proposed language amending claims 3 and 4 as follows:

> 3. A synthetic gene comprising the DNA sequence presented in Fig. 1, spanning nucleotides 1 through 1793.
>
> 4. A synthetic gene comprising the DNA sequence presented in Fig. 1, spanning nucleotides 1 through 1833.

Those claims issued as claims 13 and 14 in that form.

As we explained in our initial opinion in this case, the court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 588, 56 USPQ2d 1865, 1887 (Fed. Cir. 2000) (en banc), *cert. granted*, 121 S. Ct. 2519 (2001), held that cancellation of a claim and replacement with another claim having an added limitation had the effect of narrowing the scope of the original claim and therefore should be treated

as a claim amendment that created a total bar to the doctrine or equivalents with respect to the limitation that was in effect added to the original claim. In *Festo*, as here, the court had under consideration a claim limitation that was not present in the original independent claim but was present in an original dependent claim and was imported from the dependent claim into the independent claim that ultimately issued.

In *Festo*, one of the issued claims of the Stoll patent recited "a sleeve made of magnetizable material." *Id.* at 580, 56 USPQ2d at 1881. The independent claim of the application, claim 1, did not include that limitation, although a dependent claim, claim 8, did include it. *Id.* at 582-83, 56 USPQ2d at 1883. Following rejection of the original claims, the applicant submitted new claims, including an independent claim that contained the "magnetizable sleeve" element. That claim was subsequently allowed and issued.

In analyzing that sequence of events, we concluded that prosecution history estoppel applied because the amendment narrowed the literal scope of the original independent claim, even though the narrowing was effected through the addition of a new claim rather than through an amendment to the original claim. We explained:

> To determine whether a claim amendment gives rise to prosecution history estoppel, we first must determine whether the amendment narrowed the literal scope of the claim. Here we are presented with the situation where the added claim element was introduced through a new claim,

> instead of through an amendment to an original claim. Nevertheless, the addition of the magnetizable sleeve claim element can be said to have narrowed the scope of the original claim because the new claim replaced the original claim. Specifically, the only original independent claim, which did not recite a magnetizable sleeve, was replaced with an independent claim which does recite a magnetizable sleeve. Because the amendment narrowed the literal scope of the claim, we must determine whether Festo has established that it was made for a reason unrelated to patentability.

Festo, 234 F.3d at 587-88, 56 USPQ2d at 1887. Because Festo had not shown that the scope of the independent claim was changed for a purpose unrelated to patentability, we held that application of the doctrine of equivalents was barred as to that claim element. *Id.* at 588, 56 USPQ2d at 1888.

That analysis is equally applicable to the claims at issue in this case. As in *Festo*, the limitations at issue in this case were included in dependent application claims and were later incorporated into the independent claims that were allowed and issued. As in *Festo*, the scope of the independent claim was clearly limited when it was replaced by a claim the language of which was drawn from a prior dependent claim.

As described above, the examiner in this case made clear that in light of the unpredictability of expression of synthetic genes, demonstration of enablement was required for allowance. The examiner also was clear that when only one

synthetic gene was shown to be enabled, no broader claim scope was allowable. Faced with these rejections, Mycogen acquiesced in the examiner's proposal to cancel all claims except those specifically reciting the Figure 1 sequence. Thus, the prosecution history reveals that what the examiner ultimately proposed, and Mycogen accepted, was claim language limited to sequences taken from the preferred embodiment set forth in Figure 1. Under these circumstances, it is appropriate to limit Mycogen to the literal scope of the claims to which it agreed. We therefore conclude, as we did in our original opinion, that prosecution history estoppel applies to the Figure 1 limitations that were imported into independent claims 13 and 14 from the original dependent claims, and that Mycogen is barred from asserting the doctrine of equivalents with regard to those claim limitations.

The petition for rehearing is denied.

APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED AND DECIDED MAY 30, 2001

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

00-1127

MYCOGEN PLANT SCIENCE, INC.
and AGRIGENETICS, INC.,

Plaintiffs-Appellants,

v.

MONSANTO COMPANY,

Defendant-Appellees.

* * *

Appealed from: United States District Court for the Southern District of California
Judge Napoleon A. Jones, Jr.

DECIDED: May 30, 2001

Before CLEVENGER, BRYSON, and LINN, *Circuit Judges.*

BRYSON, *Circuit Judge.*

Mycogen Plant Science, Inc., and its licensee, Agrigenetics, Inc., (collectively "Mycogen") filed suit against the Monsanto

Company in the United States District Court for the Southern District of California, charging Monsanto with infringing Mycogen's U.S. Patent No. 5,380,831 (the '831 patent). On Monsanto's motions for summary judgment, the district court ruled, *inter alia*, that the process claims of the '831 patent are invalid under 35 U.S.C. § 102(g); that Monsanto could not have infringed Mycogen's process claims under 35 U.S.C. § 271(g) based on any process Monsanto performed before the '831 patent issued; and that prosecution history estoppel barred application of the doctrine of equivalents to the product claims of the '831 patent. On appeal, Mycogen argues that each of those rulings is wrong. For its part, Monsanto argues that the judgment of invalidity can be affirmed on the alternative ground of lack of enablement under 35 U.S.C. § 112, paragraph 1.

We conclude that the district court improperly resolved disputed questions of material fact pertaining to the issue of prior invention, and we therefore reverse the court's ruling on summary judgment that the '831 patent is invalid under 35 U.S.C. § 102(g). We decline to affirm the summary judgment of invalidity on the alternative ground of non-enablement, as urged by Monsanto, but leave to the district court the task of determining in the first instance whether there is a genuine issue of material fact as to enablement based on its assessment of the evidence presented to it in the summary judgment proceeding. We affirm the district court's ruling on the interpretation of 35 U.S.C. § 271(g) and its ruling that Monsanto is not liable for infringement under the doctrine of equivalents.

I

This case is closely related to another infringement suit, the first of two related actions involving Mycogen and Monsanto in

the District of Delaware. *Mycogen Plant Science, Inc. v. Monsanto Co.*, 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001) ("*Delaware I*"). The patents at issue in *Delaware I* were U.S. Patent No. 5,567,600 (the '600 patent) and U.S. Patent No. 5,567,862 (the '862 patent), both of which are owned by Mycogen. Those two patents are child patents of the '831 patent, which is at issue in this case. All three patents are entitled "Synthetic Insecticidal Crystal Protein Gene." The three patents have virtually identical specifications, and they contain similar claims. This court's recent decision in *Delaware I* affirmed both the district court's claim construction and the jury's verdict finding the claims of the '600 patent and the '862 patent invalid due to prior invention under 35 U.S.C. § 102(g). 243 F.3d at 1320, 58 USPQ2d at 1033.

The '831 patent, like the '600 and '862 patents, involves the technology of genetically engineering plant genes to protect plants from insect pests. The court's opinion in *Delaware I* describes the scientific background relating to the insecticidal characteristics of *Bacillus thuringiensis* ("Bt"), a naturally occurring bacterium that served as the starting point for research into the inventions and the genetic engineering techniques involved. The *Delaware I* opinion also describes most of the background facts that are material to this decision, particularly with respect to the research activities that culminated in the Mycogen patents and the competing research activities by scientists at Monsanto.

II

Mycogen appeals the district court's grant of summary judgment holding claims 1, 3, 4, 8, and 11 of the '831 patent invalid as anticipated by prior invention and holding the remaining

process claims of the '831 patent, claims 2, 5, 6, 7, 9, 10, and 12, invalid as obvious in light of the same prior work. The prior invention on which the court relied consisted of work done by scientists at Monsanto. As the grant of summary judgment was based on the court's ruling on prior invention, the validity of all 12 claims can be considered together on appeal.

Under 35 U.S.C. § 102(g)(2), an applicant is not entitled to a patent if "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376-79, 231 USPQ 81, 87-90 (Fed. Cir. 1986). An inventor can establish that he was the first to invent under section 102(g) by showing either that he was first to reduce the invention to practice or that he was first to conceive the invention and then exercised reasonable diligence in attempting to reduce the invention to practice from a date just prior to the other party's conception to the date of his reduction to practice. 35 U.S.C. § 102(g) ("In determining priority of invention ... there shall be considered ... the reasonable diligence of one who was the first to conceive and last to reduce to practice, from a time prior to conception by the other."); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996). Accordingly, for Monsanto to succeed in challenging the validity of Mycogen's '831 patent based on Monsanto's claim to prior inventorship, Monsanto must show by clear and convincing evidence both (1) that it reduced the invention to practice before Mycogen, and (2) that Mycogen did not conceive the invention first and then exercise diligence in reducing it to practice from before the date of Monsanto's conception.

Appendix B

The district court ruled that collateral estoppel from *Delaware I* required it to conclude that Monsanto had reduced the invention of the '831 patent to practice before Mycogen. The court further ruled, however, that collateral estoppel did not apply to the issue of whether Mycogen had been the first to conceive the invention and then had been diligent in reducing the invention to practice during the critical period, which the court properly defined as beginning just before Monsanto's conception and ending with Mycogen's constructive reduction to practice on September 9, 1988. Addressing the merits of that issue, the court concluded that Monsanto had established that Mycogen had not been diligent during the critical period. The court therefore granted summary judgment of invalidity based on Monsanto's prior invention.

We agree with the district court that collateral estoppel requires the court to conclude that Monsanto reduced the invention to practice before Mycogen, and that collateral estoppel does not resolve the question whether Mycogen was the first to conceive and then was diligent during the critical period. On the merits of the summary judgment question, however, we do not agree that Monsanto has met its burden of showing that there are no issues of material fact regarding whether Mycogen was the first to conceive the invention and then diligently reduce it to practice.

A

The district court concluded that collateral estoppel required it to adopt findings from the Delaware suit on two issues: claim construction and Monsanto's reduction to practice prior to Mycogen. In *Delaware I*, this court affirmed the Delaware district

court on both of those issues. 243 F.3d at 1330, 1337, 58 USPQ2d at 1041, 1047.

It is undisputed that as a result of collateral estoppel, a judgment of invalidity in one patent action renders the patent invalid in any later actions based on the same patent. *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 349-50, 169 USPQ 513, 527-28 (1971). Collateral estoppel also applies to common issues in actions involving different but related patents. *See, e.g., Amgen, Inc. v. Genetics Inst., Inc.*, 98 F.3d 1328, 1329-32, 40 USPQ2d 1524, 1524-27 (Fed. Cir. 1996) (collateral estoppel renders claims invalid when a narrower claim in a parent patent with the same specification had been held invalid as not enabled in an earlier action); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1136, 227 USPQ 543, 546 (Fed. Cir. 1985) (collateral estoppel can preclude relitigation of the same issue even in connection with different claims). Thus, the question presented here, with respect to the application of collateral estoppel, is whether any of the issues resolved in the Delaware action are the same as any of the issues presented in this case.

The independent process claim of the '831 patent recites:

> 1. A method of designing a synthetic *Bacillus thuringiensis* gene to be more highly expressed in plants, comprising the steps of:
>
> > analyzing the coding sequence of a gene derived from a *Bacillus thuringiensis* which encodes an insecticidal protein toxin, and

> modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence.

'831 patent, col. 38, ll. 25-34.

In comparison, a representative claim of the '600 patent, which was found invalid in the Delaware suit, recites:

> 1. A method of designing a synthetic *Bacillus thuringiensis* gene to be more highly expressed in plants, comprising the steps of:
>
> (a) analyzing the coding sequence of a gene derived from a *Bacillus thuringiensis* which encodes an insecticidal protein toxin,
>
> (b) modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence prior to modification, said modification comprising reducing the number of codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence,
>
> (c) inserting said modified sequence into the genome of a plant cell, and

> (d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said *Bacillus thuringiensis* gene is expressed to produce a pesticidal protein toxin.

'600 patent, col. 31, ll. 37-57.

The two steps recited in claim 1 of the '831 patent are also found in claim 1 of the '600 patent. The two claims differ in that claim 1 of the '600 patent includes two further steps in addition to the two steps that are common to both claims, and it also includes additional limitations requiring removal of a number of codons having the nucleotide bases guanine and cytosine (GC) in codon positions II and III.

With respect to claim construction, the terms of the claims of the '831 patent must be construed consistently with the same terms in the '600 patent. Claim construction was litigated in *Delaware I* before both the district court and this court, and determination of that issue was necessary to the judgment in that case.

Similarly, a finding that Monsanto reduced the four-step invention of the '600 patent to practice before September 9, 1988 (the date on which it is undisputed that Mycogen reduced the invention to practice), necessarily means that Monsanto also reduced the two-step invention of the '831 patent to practice before September 9, 1988. As with claim construction, prior

invention by Monsanto was argued before the district court and this court in *Delaware I* and was critical to the judgment.

Monsanto did not argue to the district court or to this court that collateral estoppel dictated a finding on the issues of Mycogen's prior conception and diligent reduction to practice, nor would such an argument have succeeded. Collateral estoppel does not apply to those issues, because the jury in the Delaware action could have found that the Mycogen inventors had first conceived and diligently reduced to practice the two-step invention of the '831 patent but had not conceived or diligently reduced to practice the four-step invention at issue in that case. For example, the Delaware jury could have concluded that Mycogen had not conceived the limitation of reducing the number of codons having the CG base pair in codon positions II and III or had not been diligent in inserting the modified sequence into a plant cell. Such findings would support the Delaware jury's verdict, but would not support a finding of prior invention in this case.

B

Mycogen would be considered to be the first inventor under section 102(g) if it was the first to conceive and was reasonably diligent during the critical period. In order to determine whether Mycogen should be considered the first inventor on that theory, the district court addressed the following three issues, each of which we discuss below: (1) when Mycogen conceived the claimed invention; (2) when Monsanto conceived the claimed invention; and (3) whether Mycogen was diligent during the critical period between Monsanto's conception and Mycogen's reduction to practice.

Appendix B

1

The district court first concluded that there was a disputed issue of material fact as to when Mycogen conceived the claimed invention. We agree with that conclusion for the reasons given by the court. The court analyzed the evidence relating to the date of Mycogen's conception, including testimony by Dr. Adang and Dr. Murray that they conceived the invention encompassed within claims 1 and 11 of the '831 patent in November 1985, and testimony by three ex-employees who corroborated the inventors' testimony. The court properly concluded that Mycogen's evidence was sufficient to raise a genuine issue of fact as to whether Mycogen conceived the invention as early as November 1985. Because that date was before Monsanto claims to have conceived the invention, the district court properly assumed for purposes of summary judgment that Mycogen was the first to conceive.

2

Having found that there was evidence from which a fact-finder could conclude that Mycogen was the first to conceive the invention of the '831 patent, the district court turned to the question whether Mycogen was diligent in attempting to reduce the invention to practice during the critical period. That inquiry, in turn, required the court to consider when Monsanto conceived the invention, and thus when the critical period of diligence began for Mycogen.

Mycogen argues on appeal that the district court erred when it concluded for purposes of summary judgment that Monsanto conceived the patented invention by October 1986. The district

court stated that "Mycogen cannot dispute that by October of 1986, Monsanto had the idea to solve the Bt expression problem by creating a synthetic Bt gene modified to contain a greater number of codons preferred by plants." The basis of the court's conclusion was testimony by the Monsanto inventors, Dr. Fischhoff and Dr. Perlak, and a memorandum prepared by Dr. Fischhoff on October 30, 1986, that documented their ideas at that time.

While we agree with Monsanto that the October 30, 1986, memorandum and testimony by Drs. Fischhoff and Perlak establish that Monsanto scientists had conceived the idea of a synthetic gene, that does not establish that they had conceived, as the claims require, that the gene would be modified by increasing the number of plant-preferred codons rather than by eliminating particular destabilizing codon sequences. On its face, the October 30, 1986, memorandum focuses on the removal of adenine and thymine base pairs (A+T). It concludes that the problem of low Bt expression was caused by low levels of mRNA and that the instability of the mRNA was a "function of its high A+T content." Monsanto asserts that the statement in the memorandum that gene segments should be replaced with "codons of lower A+T content" necessarily means that those replacement codons would be preferred by plants. However, whether a codon has lower A+T content and whether a codon occurs more frequently in a particular plant are two different concepts. As Mycogen demonstrates in its brief, in some instances eliminating codons with a high A+T content results in codons that are *less* plant-like.

Although the 1986 memorandum is not totally silent as to the codons found in plants, the memorandum does not state that

gains in Bt expression are likely to result from making the codon frequency of the synthetic gene more plant-like. Nothing in the memorandum suggests that examining the codon frequencies in plants is part of the solution to the problem of low expression or that such information is necessary to practice the invention. Monsanto points to a 1984 Monsanto report that discusses the possibility that determining the frequency with which codons are used by a particular organism may make it possible to obtain higher rates of expression of desired proteins. The October 1986 memorandum, however, does not refer to the 1984 report or the ideas it contains.

Nor does the inventor testimony clearly establish that the Monsanto scientists had conceived the invention by October 1986. In his testimony at the *Delaware I* trial, Dr. Perlak accurately described the October 1986 memorandum as teaching the two strategies of replacing particular AT-rich regions of the native Bt gene or synthesizing an entire gene of predetermined sequence and base composition. The second strategy would involve replacing segments up to and including the entire native Bt gene with chemically synthesized segments that coded for the same amino acids but utilized codons lower in AT content. Dr. Perlak did not, however, testify that the memorandum suggested the use of plant-preferred codons, although he later filed a declaration in which he stated that the implication of the memorandum was to suggest substituting plant-preferred codons for disfavored codons.

Dr. Perlak further testified in the *Delaware I* case that in 1987 he used a codon usage table to identify plant-preferred codons as he was designing Bt genes to put into plants. His testimony supports the inference that it was in late 1987 that he

focused on the strategy of designing a gene with plant-preferred codons. According to his testimony, he referred to that strategy in his laboratory notebook entry for September 8, 1987. The entry for that day states: "Problem: Poor expression of Bt.K HD-1 toxic genes in plants. Possible causes: (1) regions of AT rich induced instability in RNA; (2) overall AT too rich; (3) little used codons by plants found in gene. Solution: Order a new gene synthesized, using plant-preferred codons."

Like Dr. Perlak, Dr. Fischhoff described the status of conception in October 1986 as removing parts of the gene sequence such as polyadenylation sites and other parts of the gene that were made up largely of A and T bases, which are not commonly found in plants. He explained that it followed that upon removing some such sequence a researcher would necessarily replace it with something more plant-like. He did not testify, however, that as of October 1986 he and Dr. Perlak had conceived the idea of increasing the number of plant-preferred codons as the key to solving the problem of low protein expression of the Bt gene in plants.

The fact that removing portions of the native Bt gene having high concentrations of A and T bases generally resulted in the substitution of codons preferred by plants is not enough to constitute conception, if that result was merely a by-product of the Monsanto scientists' research program, rather than an independent objective. Conception requires contemporaneous recognition and appreciation of the limitations of the claimed invention, not merely fortuitous inherency. *See Heard v. Burton*, 333 F.2d 239, 243-44, 142 USPQ 97, 100 (CCPA 1964); *see also Estee Lauder, Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997). This principle

also applies to the other component of invention, reduction to practice, as discussed in detail in *Delaware I. See* 243 F.3d at 1336, 58 USPQ2d at 1046.

To be sure, Monsanto offered testimony by several co-workers who testified that it was their understanding that one of the goals of Drs. Perlak and Fischhoff was "to move the codon usage more towards what the plants use as opposed to what the bacterial sequence was" and to use "codons from plants to replace these AT-rich ones to maintain that protein sequence." While that testimony supports Monsanto's position on the issue of conception, it is not specific as to the dates on which Drs. Perlak and Fischhoff conceived the "plant-preferred codon" approach to the problem.

In sum, while Monsanto presented evidence that could support a finding of conception by October 1986, Mycogen has identified sufficient weaknesses in that evidence that a reasonable fact-finder could conclude that Monsanto had not conceived the invention as of that time. Accordingly, we do not agree that the record supports the finding that, as a matter of law, there is clear and convincing evidence that Monsanto had conceived the invention by October 1986.

The question remains whether the record supports any particular date as the date of Monsanto's conception as a matter of law. Monsanto argues that its conception was established by September 8, 1987, at the latest. That was the date on which Dr. Perlak pasted the design of a gene in his lab notebook and wrote that the solution was to "order a new gene synthesized, using plant preferred codons." That statement shows conception of the invention in a clear and convincing way, and Mycogen has

not argued to the contrary. Accordingly, we conclude that the record compels the conclusion that Monsanto had conceived the invention by September 8, 1987, at the latest.

3

That conclusion requires us to consider a third question — whether Mycogen demonstrated diligence in its effort to reduce the invention to practice from just before September 8, 1987, until it constructively reduced the invention to practice by filing the parent application to the '831 patent on September 9, 1988. The district court concluded that during at least a portion of that period, Mycogen's research efforts were not directed to the claimed invention. Instead, the court concluded, Mycogen was pursuing a different strategy — trying to find particular problem regions of the Bt gene, sometimes called "death sequences," which were inhibiting expression. In the court's view, Mycogen's goal in searching out specific problem regions of the Bt gene was not related to rebuilding the entire gene to make it more plant-like. Because Mycogen was "working on unrelated experiments," the court concluded, it was "clearly not diligent."

Mycogen argues that the district court erred when it concluded that looking for specific problem sequences to alter within the Bt gene did not constitute diligence in reducing to practice the invention of rebuilding the entire gene to make it more plant-like. We disagree. The invention was not simply to modify the Bt gene so that a plant would express Bt toxin. Instead, the invention was to devise a method of designing a synthetic Bt gene by analyzing the coding sequence of the native Bt gene and modifying a portion of that coding sequence so that the modified sequence would contain a greater number of plant-

preferred codons. Accordingly, Mycogen's research efforts directed at identifying specific problem areas that were inhibiting expression did not constitute diligence toward reduction to practice of the claimed invention.

That conclusion does not end the inquiry, however, because not all of Mycogen's work was directed at the concept of locating and making changes to particular problem areas of the native Bt gene. Dr. Murray, one of the inventors of the '831 patent, began compiling codon usage tables on August 27, 1987, prior to the beginning of the critical period that we have defined for summary judgment purposes. She testified that she put together a codon usage table at that time, "to use to show people so we could proceed with rebuilding the gene," and that her work at that time was the beginning of the effort to create the tables that were ultimately included in the '831 patent. Her declaration states that she "continued to work on obtaining gene sequences for the purpose of generating and compiling the codon usage tables from August 27, 1987 to June 28, 1988," and that the "preparation of the codon usage tables was carried out without any significant gaps or delays."

Those statements are supported by several notebook entries. In particular, Dr. Murray's entries for August 27, 1987, indicate that she developed codon usage tables for both the Bt bacterium and for plants. She pasted an article into her notebook that showed, in her words, that changing "*favored* codon usage to *unfavored* codon usage destabilized the gene's translation," and she wrote that the "general idea is we should change the coding sequence of the Bt gene to make it look more like a plant gene." Later entries also demonstrate continued work directed at creating codon usage tables.

Appendix B

Monsanto relies on the "admission" by Dr. Adang, another one of the inventors of the '831 patent, that his company did not decide to undertake synthesis of a complete Bt gene until January 1988. However, the corporate decision to focus principally on another line of inquiry is less important than the acts of the individual inventors in attempting to reduce the invention to practice. Dr. Murray testified that although funding for synthesizing the entire gene was not approved until March 1988, her work on codon usage tables beginning in August 1987 was directed at determining how to structure a synthetic Bt gene to make it more plant-like than the native Bt gene. Her testimony is supported by her laboratory notebook entry of March 3, 1988, which states that the Mycogen scientists held a meeting on the Bt project and "decided to push ahead with rebuilding Bt gene based on codon usage tables (I developed these)." The same entry states that the "effort to look for so-called death sequences ... will also proceed." Moreover, Dr. Adang testified that the synthetic gene that he began to design in January 1988 was prepared using Dr. Murray's codon usage tables. The evidence before the court further showed that once the corporate decision had been made to synthesize a modified Bt gene, Dr. Murray and the other Mycogen inventors continued to work on the invention until its constructive reduction to practice in September 1988.

In order to prevail on this issue for summary judgment purposes, Monsanto must show that a reasonable fact-finder would have to conclude, by clear and convincing evidence, that the Mycogen inventors were not diligent during the critical period. In light of the documentary and testimonial evidence before the district court, we hold that there is a triable issue of fact as to whether Dr. Murray's efforts beginning in August 1987 constituted reasonable diligence in attempting to reduce the invention to

practice. To be sure, the evidence suggests that there were short gaps in the work that was done on the codon usage tables during the critical period. Proof of reasonable diligence, however, does not require a party to work constantly on the invention or to drop all other work. *See Bey v. Kollonitsch*, 806 F.2d 1024, 1028, 231 USPQ 967, 970 (Fed. Cir. 1986); *In re Nelson*, 420 F.2d 1079, 1081, 164 USPQ 458, 459 (CCPA 1970); *Gould v. Schawlow*, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966). Thus, we conclude that the evidence of record raises a genuine issue of material fact as to whether Mycogen was diligent throughout the critical period. We therefore reverse the district court's grant of summary judgment that the process claims of the '831 patent are invalid as anticipated by prior invention by Monsanto or as obvious in light of the same prior invention.

III

Monsanto argues that, in the event the '831 process claims are not found invalid under section 102(g), we should nonetheless affirm the district court's summary judgment of invalidity on the ground that the claims are not enabled under 35 U.S.C. § 112, paragraph 1. Monsanto previously had moved for summary judgment of invalidity because of lack of enablement. The district court, however, did not reach that issue, finding it to be moot in light of the court's judgment that the claims were invalid under section 102(g). Because we have reversed the district court's summary judgment of invalidity under section 102(g), we consider Monsanto's alternative basis to affirm the decision.

Appendix B

A

Monsanto's first argument is based on the doctrine of collateral estoppel. The district court in *Delaware I* granted judgment as a matter of law that the claims of the '600 patent were invalid as not enabled. Monsanto argues that based on that judgment the process claims of the '831 patent must also be found to be not enabled.

The *Delaware I* judgment does not give rise to collateral estoppel on enablement for two reasons. First, this court did not reach the issue of enablement when the *Delaware I* judgment was appealed to this court. *Delaware I*, 243 F.3d at 1337, 58 USPQ2d at 1047. Accordingly, that judgment does not preclude reconsideration of the issue in other actions. *See* 18 Charles Alan Wright et al., *Federal Practice and Procedure: Jurisdiction* § 4421 n.25 (2d ed. 1988 & 2000 supp.) ("once an appellate court has affirmed on one ground and passed over another, preclusion does not attach to the ground omitted from its decision"). Second, because the '600 patent recites a four-step claim and the '831 patent recites a two-step claim, a finding that the four-step claim was not enabled does not necessarily mean that the two-step claim was not enabled. Thus, even if this court had addressed and upheld the enablement ruling in *Delaware I*, collateral estoppel would not apply to the enablement issue in this case.

B

Monsanto further contends that we should uphold the summary judgment of invalidity based on lack of enablement even though the district court did not reach the enablement issue in its

summary judgment ruling. We are reluctant to decide an issue that the district court has declined to address, at least in a case such as this one in which the resolution of the issue is not plain on its face.

Monsanto's argument on appeal is that the claims are too broad to be enabled by a specification that provides only one example of an embodiment of the invention. The specification of the '831 patent, however, includes more than just a single example: it contains codon usage tables, recommendations on the preferred level of homology, and means for calculating deviation of the frequency of preferred codon usage. The proper resolution of the enablement issue is thus not sufficiently clear for us to direct the district court to enter summary judgment on that issue before the district court has addressed it. Accordingly, we leave it to the district court to determine whether there is a genuine issue of material fact as to enablement.

IV

Mycogen also appeals from the district court's ruling on summary judgment that Monsanto could not be liable under 35 U.S.C. § 271(g) for selling products containing genes made before the '831 patent issued. The district court concluded that section 271(g) does not apply to products made by a process that was not patented at the time the products were made, even though the products were sold after the patent issued. Mycogen argues on appeal that section 271(g) applies to the post-issuance sale of any product made by a patented process, regardless of when the accused infringer performed the process. This issue presents a purely legal question of statutory construction.

Appendix B

Section 271(g) provides:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States, a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.

Mycogen's primary argument is that the statute provides that liability attaches if the importation, offer to sell, sale, or use of the product occurs during the patent term but does not refer to the process itself being performed, or the product being made, during the term of the patent. Thus, Mycogen asserts, even if Monsanto did not perform the process claimed by the '831 patent after the patent issued, Monsanto would still be liable if it sold or used such products during the patent term.

Mycogen supports its argument by citing *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553, 38 USPQ2d 1321 (Fed. Cir. 1996). That case, however, does not answer the question posed by this one. In the *Bio-Technology General* case, the court held that one who imported products made by a patented process was liable under section 271(g) even though the process was performed prior to the enactment of the statute. 80 F.3d at 1560, 38 USPQ2d at 1326. In reaching that decision, the court focused on the importation of the product, rather than its manufacture, as the triggering event. The court concluded that because liability did not attach until importation occurred, application of the statute to products that were made before the effective date of the statute did not create a retroactivity problem.

Id. Because the process was performed in 1983, within the term of the 1982-issued patent, the court had no occasion to consider the question presented here — whether section 271(g) would apply to the importation of a product produced by a process that was performed before the issuance of the patent. *Id.*

Monsanto counters that while it is true that the use must occur during the patent term, the statute also requires that the product be "made by a process patented in the United States," and that products made *before* the patent issues are not made by a "process patented in the United States." In other words, Monsanto argues that "patented in the United States" means "*then* patented in the United States," not "*later* patented in the United States."

We think Monsanto has the better of the argument based on the language of section 271(g). In the phrase "a product which is made by a process patented in the United States" the verbs "made" and "patented" are part of a parallel construction, which suggests that for infringement to be found the process must be patented at the time the product is made.

The legislative history of the statute also supports the construction adopted by the district court. The congressional reports make clear that the principal purpose of the statute was to prevent a patent owner's competitors from avoiding the patent by producing products outside the United States and then importing them. *See, e.g.*, S. Rep. No. 100-388, at 33 (1988); H.R. Conf. Rep. No. 100-576, at 1085-87 (1988), *reprinted in* 1988 U.S.C.C.A.N. 1574, 2118-20. In that regard, the statute was intended to grant patent holders the same protection against overseas infringers as they already enjoyed against domestic

entities. Because domestic entities do not infringe a process patent if they practice the process before the beginning of the patent term, even if they sell the products of the process during the term of the patent, *see Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773-74, 28 USPQ2d 1378, 1381-82 (Fed. Cir. 1993), parallel treatment of overseas entities indicates that the statute does not reach pre-issuance use of the later-patented process.

Mycogen argues that Monsanto's approach defines too narrowly the loophole that Congress intended to fix. Instead, Mycogen contends, Congress meant to impose liability for commercializing a process in addition to practicing it. The legislative history however, does not support Mycogen's position. Mycogen's only citation to the history of the statute is to a bill introduced five years before the date of enactment that expressly required the product to be made during the term of the patent. H.R. 4526, 98th Cong. (1983). Mycogen asks us to infer from the difference between the language of that bill and the language ultimately enacted that Congress altered the language in order to expand the reach of the statute. Without much stronger support in the legislative history, however, that inference is too weak to overcome the construction dictated by the plain terms of the statute that Congress enacted.

We hold, therefore, that in imposing liability for selling or using products "made by a process patented in the United States," section 271(g) requires that the patent be issued and in force at the time that the process is practiced and the product is made. Accordingly, we affirm the district court's grant of summary judgment that Monsanto did not infringe Mycogen's process claims based on any process it performed before the patent issued.

Appendix B

V

In the district court, Mycogen conceded that Monsanto did not literally infringe product claims 13 and 14 of the '831 patent. Mycogen, however, asserted infringement of those claims under the doctrine of equivalents. The district court ruled on summary judgment that prosecution history estops Mycogen from relying on the doctrine of equivalents to show infringement of those claims, and Mycogen challenges that ruling on appeal.

The two claims at issue read as follows:

> 13. A synthetic gene comprising the DNA sequence presented in Fig. 1, spanning nucleotides 1 through 1793.
>
> 14. A synthetic gene comprising the DNA sequence presented in Fig. 1, spanning nucleotides 1 through 1833.

'831 patent, col. 40, ll. 3-8. Both claims refer to figure 1 of the '831 patent, which graphically displays a genetic sequence of 1,833 specific nucleotides. These are the only two product claims in the '831 patent.

During the course of prosecution of the '831 patent, Mycogen cancelled several claims that were originally submitted to the PTO. Among the claims canceled were application claims 1, 2, 5, and 6:

> a1. A synthetic gene designed to be highly expressed in plants comprising a DNA sequence encoding an insecticidal protein which is functionally equivalent to a native insecticidal protein of Bt.

Appendix B

a2. A synthetic gene of claim 1 wherein said DNA sequence is at least about 85% homologous to a native insecticidal protein gene of Bt.

a5. A synthetic gene of claim 1 wherein the overall frequency of preferred codon usage within the entire coding region of said synthetic gene is within about 75% of the frequency of codon usage preferred in plants.

a6. A synthetic gene of claim 1 wherein the overall frequency of preferred codon usage within the entire coding region of said synthetic gene is within about 90% of the frequency of codon usage preferred in plants.

The prosecution history shows that those claims were rejected on the grounds of obviousness and lack of enablement, and that they were replaced by product claims 13 and 14.

This court recently held in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 563, 56 USPQ2d 1865, 1868 (Fed. Cir. 2000), that "an amendment that narrows the scope of a claim for any reason related to the statutory requirements of a patent will give rise to prosecution history estoppel with respect to the amended claim element." In this case, the product claims were not amended. Instead, the initial claims defining the synthetic gene by a broadly specified DNA sequence were cancelled and replaced with claims containing a more narrowly specified DNA sequence. The more narrowly specified claims then issued with the '831 patent. We do not discern any legally significant difference between canceling a claim

having a broad limitation and replacing it with a claim having a narrower limitation, and amending a claim to narrow a limitation. To do so would place form over substance and would undermine the rules governing prosecution history estoppel laid out in *Festo* by allowing patent applicants simply to cancel and replace claims for reasons of patentability rather than to amend them. This notion is not new, as this court has previously treated canceling and replacing claims as analogous to amending them. *See Haynes Int'l, Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 1578-79, 28 USPQ2d 1652, 1656-57 (Fed. Cir. 1993). In fact, some of the "amendments" at issue in *Festo* involved cancellations. 234 F.3d at 588, 56 USPQ2d at 1887.

On appeal, Mycogen does not argue that the district court erred in concluding that the cancellation of the product claims with the broad DNA sequence in favor of claims with a more narrowly defined DNA sequence gave rise to prosecution history estoppel. Instead, Mycogen argues that despite the estoppel the district court erred when it did not hold that claims 13 and 14 were entitled to some range of equivalents. That argument, however, is at odds with our decision in *Festo*. When a claim amendment (or in this case the cancellation of a claim with a broad limitation in favor of one with a narrower limitation) creates prosecution history estoppel, *no* range of equivalents is available for the amended claim limitation. *Festo*, 234 F.3d at 564, 56 USPQ2d at 1868. Accordingly, we affirm the district court's ruling that Mycogen is estopped from asserting the doctrine of equivalents with respect to claims 13 and 14.

Each side shall bear its own costs for this appeal.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.

APPENDIX C — JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA DATED, ENTERED AND FILED NOVEMBER 15, 1999

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

JUDGMENT IN A CIVIL CASE

Case Number 3:95-cv-00653

Mycogen Plant – plaintiff

v.

Monsanto Company – defendant

* * *

_x_ DECISION BY COURT. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered

IT IS ORDERED AND ADJUDGED the stay is lifted; granting defendant's motion for summary judgment of invalidity under 35 U.S.C. 102(g) and 103 pursuant to FRCP 56 [274-1], denying the motion for summary judgment of invalidity of claims 1-12 of U.S. Patent No. 5,380,831 [271-1] as moot.

11/15/99
Date

Roberta Westdal
Clerk

s/ J. LaViolette
by J. LaViolette, Deputy Clerk

Entered on 11/15/99

APPENDIX D — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA LIFTING STAY AND GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT DATED AND FILED NOVEMBER 10, 1999

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

CASE NO. 95-CV-653-J (LSP)

MYCOGEN PLANT SCIENCE, INC., a Delaware corp., and AGRIGENETICS, INC., a Delaware corp.,

Plaintiff,

vs.

MONSANTO COMPANY, a Delaware corp.,

Defendant.

ORDER LIFTINGSTAY

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT UNDER 35 U.S.C §§ 102(g) AND 103

ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT UNDER 35 U.S.C. § 112 AS MOOT

[docket #'s 271, 274, 292]

Appendix D

This matter comes before the Court on Defendant Monsanto Company's ("Monsanto") motion for summary judgment. Monsanto contends that the method claims of Plaintiff Mycogen Company's ("Mycogen") patent in suit, U.S. Patent No. 5,380,831 (" '831 Patent") are invalid under 35 U.S.C. §§ 102(g) and 103, because it invented the subject matter of the independent claims 1 and 11 before Mycogen.

Monsanto also brings a second motion for summary judgment under 35 U.S.C. § 112 arguing that the method claims in Mycogen's '831 patent are invalid because they fail to enable a practitioner of ordinary skill in the relevant art to practice the full scope of the claim invention without undue experimentation. On May 4, 1998, this Court heard extensive oral argument on the matter. The Court instructed from the bench that this action would be stayed until the post-trial motions in a related case in Delaware were complete. On September 8, 1999, Judge McKelvie of the District of Delaware denied Mycogen's motion for judgment as a matter of law that two related patents were not invalid due to prior invention. Accordingly, this Court LIFTS the STAY and GRANTS Monsanto's motion for summary judgment pursuant to 35 U.S.C. §§ 102(g) and 103 and DENIES as moot the motion for summary judgment under 35 U.S.C. § 112.

I. Background

A. Procedural History

On May 23, 1995, Mycogen filed a suit for infringement of its '831 patent. Since the initial filing, this Court has granted several of Monsanto's motions, narrowing the issues

remaining in this case. After analyzing the legislative history of 35 U.S.C. § 271(g), this Court held that there could be no infringement arising from any gene modification activities undertaken by Monsanto prior to the issuance of the '831 patent. Moreover, this Court held that Mycogen was barred by the doctrine of prosecution history estoppel from relying on the doctrine of equivalents to prove infringement with respect to the two product claims (claims 13 and 14). This Court also held that the claims of the '831 patent cannot be construed for purposes of infringement to cover abstract designing activities such as the writing of gene sequences or the creation of genes in the natural growth of already existing plants.

B. The Inventions

The Court takes the following facts relating to the inventions and the technology from the parties' briefs. The '831 patent relates to a genetically engineered gene derived from a species of bacteria called *Bacillus thuringiensis* ("Bt"). Bt bacteria occur naturally in social microorganisms and produce proteins that are toxic to insects but not harmful to humans, animals, or agriculturally useful insects, such as bees and ladybugs. For many years, the typical solution to destruction of agricultural crops by insects was to spray this Bt toxin on crops. But, spraying was not always effective because many of the targeted insects actually bore into the plants and avoided the pesticide. As set forth in the specification of the '831 patent, scientists realized that they could isolate the DNA sequence in the Bt bacteria, otherwise known as that native Bt genes, which encodes the insecticide protein. Scientists could then insert the DNA sequence or

Bt genes into the host plant causing the plant to produce the protein itself. While Bt genes worked well in their natural hosts, when they were placed in plant hosts, the plants did not respond and produce enough Bt protein to be insecticidal. The scientists needed to "jump-start" the recalcitrant gene so it would "express" in plants and make the protein. The scientists realized that they could modify the coding sequence of the native Bt gene to make it more "plant like" by inserting the synthetic Bt gene with the modified sequence into the DNA of the plants. Once in the plant, the synthetic Bt gene produced the desired Bt insecticidal protein toxin. This invention is the basis of the '831 patent. To further understand the nature of this patent, some technical background is necessary.

C. Technical Background

The '831 patent delineates a process for modifying the coding sequence of a gene derived from the naturally occurring Bt. To begin with, a **gene** is a section of DNA. Genes contain the genetic material which directs the production of **amino acids** which are the building blocks of **protein**. Proteins are what ultimately make particular cells perform their function within an organism. The genetic material of genes and DNA are long chains of chemical building blocks called **nucleotides**. There are four types of nucleotides: adenine (A), guanine (G), cytosine (C), and thymine (T). The sequence of nucleotides that make up a particular DNA molecule or gene is represented by listing the nucleotides in the order they occur. For example, a section of a gene's DNA can be represented as: ATGGCTGCAGAC.

This string of nucleotides can be further divided into **codons**. A codon is a group of three adjacent nucleotides.

Appendix D

Referring to the example above the there are four codons: 1) ATG; 2) GCT; 3) GCA; and 4) GAC.

Codons tell the cell to select certain **amino acids**. Amino acids are the "building blocks" of proteins. There are only 20 different types of amino acids. A protein is made up of any number of these amino acids. Given that there are four types of nucleotides, there are 64 possible combinations of three, and thus 64 possible codons. Since there are more codons than amino acids, several types of codons can specify the same amino acid. For example, GCG, GCA, GCT, and GCC all specify the same amino acid Alanine. Given that more than one codon can specify a particular amino acid, scientists call the genetic code **redundant**. If scientists alter the DNA structure and replace the codon GCG in a gene with the codon GCA, they have altered the coding sequence of the gene, but the coding sequence still specifies the same amino acid, Alanine, and as a result, the organism produces an identical protein.

Each organism naturally prefers certain codons over others. As a result, the codons that make amino acids do not occur with equal frequency in all organisms. The **frequency** of codon usage in an organism refers to the number of times that a given codon is used to code for an amino acid in comparison to the other synonymous codons which code for the same amino acids.

With respect to the Bt gene, scientists discovered that the codons preferred by plants are different than those preferred by the Bt bacteria. Hence, inserting the native Bt gene into the DNA of plants did not result in the desired

high production of the insecticidal Bt protein toxin. Mycogen alleges that its scientists conceived of the invention of modifying the coding sequence of the native Bt gene so it would express better in plants, i.e., be more "plant-like." Given the redundancy of the genetic code, the scientists could modify the codons of the native Bt gene to make it better expressed in plants while at the same time producing the same or similar sequence of amino acids and the desired Bt toxin. For example, the GCA codon appears 50% of the time in the Bt bacteria when the amino acid alanine is specified. But, in a dicot plant, meaning a broad leaf plant such as cotton, tobacco, or tomato, the GCA codon only appears about 25% of the time.

Mycogen claims that there are two different ways to accomplish this goal. The first is to modify the coding sequence of a gene derived from Bt to increase the overall number of codons preferred by the plant, i.e., claim 1. In short, the goal in the first method is to replace the codons with the one codon most preferred by the plant host. The second way is to modify the coding sequence of a gene derived from Bt to have an overall frequency of codon usage that more closely resembles the overall frequency of codon usage preferred by plants, e.g., claim 11. In other words, this second method changes the codons to appear in a distribution which more closely resembles the distribution in the plant.

These two methods were considered by Judge McKelvie who held a Markman hearing. After considering extrinsic evidence, he held that the claim for a greater number limitation requires nothing different than the greater frequency limitation. Hence, with this interpretation of the claims, Monsanto must

have understood that the newly- created synthetic gene has a higher number of codons, whose frequency in the native Bt was lower, such that the synthetic gene has an overall distribution of codons usage that is closer to the intended plant. (Pl.'s Mem. Ex. 1 at 28-29). Mycogen disputes this interpretation and has challenged it in post-trial motions, but seems to admit that it would be controlling here.[1]

Additionally, Mycogen scientists realized that certain sequences should be avoided for the Bt gene to express better in plants. For example, sequences termed "plant polyadenylation signals" had to be eliminated. This is found in Claim 4 of the '831 patent.

D. Related Patents and Suits

The '831 patent at issue is the parent of two other Mycogen patents, U.S. Patents Nos. 5,567,600 and 5,567,862 (" '600 and '862 Patents"). The '831 patent is entitled "Synthetic Insectidical Crystal Protein Gene." The twelve claims of the '831 patent are directed to a method of tailoring synthetic Bt genes so they produce an effective amount of insect toxin in plants which provides protection against insects. In short, the patent covers a method of designing a synthetic Bt gene. The '600 and '862 patents claim this process of creating a more plant-like synthetic Bt gene, as well as the resulting cells and plants. Like the '831 patent, each is entitled, "Synthetic Insecticidal Crystal Protein Gene." The first page of the '600 patent indicates that it is a continuation

1. Regardless, Judge McKelvie ruling on claim interpretations is binding on this Court given the doctrine of collateral estoppel. *See* discussion *infra* in section III, part B.

in part of the '831 patent. In addition to the method of design of the synthetic gene (found in the '831 Patent), the '600 patent claims the process of inserting this gene in a plant cell and maintaining the cell. The '862 patent states that it is a division of the '831 patent. It claims the resulting plant cell, its progeny cells, plants, and seeds. Thus, much of the terms and claims of the patents are identical, as well as most of the specifications.

The '600 and '862 patents were the subject of a patent infringement suit filed by Mycogen against Monsanto in Delaware. The issue of prior inventorship of those patents was tried to a jury. On February 5, 1998, the Delaware court entered a judgment declaring that the '600 and '862 patents are invalid based upon the jury's determination that Monsanto was the first to invent the technology underlying those patents. The Delaware Judgment was the subject of several post-trial motions. Following the entry of judgment, under FED. R. CIV. P. 50 & 59, Mycogen filed post-trial motions for Judgment as a Matter of Law (JML) and New Trial. One of the grounds for this motion is that the jury reached inconsistent verdicts. Additionally, during the Delaware litigation, Monsanto filed a summary judgment of invalidity under § 112 with respect to the '600 and '862 patents that raised substantially the same legal issues as the current motion before this Court for invalidity under § 112. The Delaware district court denied the motion and allowed the case to be heard by the jury. The jury did not address this invalidity defense as it found the patents were not infringed because of Monsanto's prior invention. As a result, Monsanto renewed its prior summary judgment motion as a post-trial JML motion in the Delaware case. On September 8, 1999, the Delaware Court upheld

the jury's determination that Monsanto was the prior inventor. Judge McKelvie wrote, "the court finds that there is [a] legally sufficient evidentiary basis for a reasonable jury to find that the claims of the '600 and '862 patents were invalid due to prior invention by Monsanto before the filing date of Mycogen's patents." *Mycogen Plant Science, Inc. and Agrigenetics, Inc. v. Monsanto Co., et al.*, No. 96-505-RRM, slip. op. at 87 (D. Del. Sept. 8, 1999).

II. Legal Standards

A. Fed. R. Civ. P. 56(b)

Pursuant to Fed. R. Civ. P. 56(b), "[a] party against whom a claim, counterclaim, or cross-claim is asserted or a declaratory judgment is sought may, at any time, move with or without supporting affidavits for a summary judgment in the party's favor as to all or any part thereof." The standards and procedures for granting partial summary judgment, also known as summary adjudication, are the same as those for summary judgment. Accordingly, the Court may grant summary adjudication upon a showing that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The moving party bears the initial burden of demonstrating that it is entitled to summary adjudication. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157-61 (1970).

If the nonmoving party will bear the burden of proof at trial, the moving party must demonstrate that summary adjudication is appropriate by submitting proof that negates an essential element of the nonmoving party's claim, or by

affirmatively demonstrating the nonmoving party's inability to produce sufficient evidence to make out a claim at trial. *Celotex*, 477 U.S. at 332 (Brennan, J., dissenting). If the moving party meets this initial burden of production, the nonmoving party must go beyond the pleadings and offer admissible evidence such that a reasonable jury could find for the nonmoving party by the appropriate standard of proof. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). The Court shall consider all admissible affidavits and supplemental documents submitted on a motion for summary adjudication. *See Connick Teachers Ins. and Annuity Ass'n*, 784 F.2d 1018, 1020 (9th Cir.), *cert. denied*, 479 U.S. 822 (1986). This includes discovery documents such as answers to deposition questions and interrogatories. FED. R. CIV. P. 56(c). The Court, however, does not weigh evidence or make credibility determinations on a motion for summary adjudication. The inferences to be drawn from the underlying facts must be viewed in the light most favorable to the nonmoving party. *Anderson*, 477 U.S. at 255.

B. 35 U.S.C. § 102(g)

Monsanto claims that the method claims of the '831 Patent are invalid because Monsanto invented the underlying technology first. Under 35 U.S.C. § 102(g), a person is entitled to a patent unless "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed or concealed it." 35 U.S.C. § 102(g). When two parties claim to invent the same subject matter, priority of invention "goes to the first party to **reduce** the invention to practice unless the other party can show that it was the first to **conceive** of the invention

and that it exercised **reasonable diligence** in reducing it to practice." *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) (emphasis added) (quoting *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993)). Monsanto has the burden of proving prior inventorship as defined by § 102(g), meaning that it must show there is no genuine issue of material fact as to all three elements of the defense: 1) reduction, and 2) lack of conception and/or 3) lack of reasonable diligence. *Lutzker v. Plet*, 843 F.2d 1364, 1366 (Fed. Cir. 1988); *Meyers v. Asics Corp.*, 974 F.2d 1304, 1306 (Fed. Cir. 1992). Monsanto also has the burden to prove its patent invalidity defense by clear and convincing evidence because issued patents carry a statutory presumption of validity. 35 U.S.C. § 282; *Tillotson, Ltd. v. Walbro Corp.*, 831 F.2d 1033, 1036 (Fed. Cir. 1987).

III. Reduction To Practice

A. Legal Standard

An invention is reduced to practice when the alleged infringer "demonstrates that the invention is suitable for its intended purpose." *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994) (quoting *In re Dardick*, 496 F.2d 1234, 1238 (C.C.P.A. 1974)). A reduction to practice that inherently embodied a claimed element is not enough. *Estee Lauder v. L'Oreal*, 129 F.3d 588, 593 (Fed. Cir. 1997). "It is well settled that conception and reduction to practice cannot be established nunc pro tunc. There must be contemporaneous recognition and appreciation of the invention present in the counts." *Id.* (citing *Breen v. Henshaw*, 472 F.2d 398, 401 (C.C.P.A. 1973). In short, an inventor must establish that he

or she appreciated the subject matter and knew the invention would work. *Silvestri v. Grant*, 496 F.2d 593, 599 (C.C.P.A. 1974). This appreciation requirement does not require a showing that the Defendant understood that the invention corresponded exactly to the language of the patent; an appreciation of the subject matter is sufficient. *Id.* Moreover, reduction to practice does not require that the invention "be in a commercially satisfactory stage of development." *Scott*, 34 F.3d at 1061 (quoting *In re Dardick*, 496 F.2d 1234, 1238 (C.C.P.A. 1974). To show the requisite reduction to practice, a Defendant cannot rely solely on the testimony or documents of the claimed inventors. Inventor testimony must be corroborated. *Hahn v. Wong*, 892 F.2d 1028, 1032-33 (Fed. Cir. 1989). Such evidence may consist of testimony of a witness, other than the inventor, the actual reduction to practice, or it may consist of surrounding facts and circumstances independent of information received from the inventor. *Id.* (citing *Reese v. Hurst v. Wiewioriwski*, 661 F.2d 1222, 1225 (C.C.P.A. 1981). Courts apply the "rule of reason" when considering the adequacy of corroborative testimony for reduction to practice. *Berges v. Gottstein*, 618 F.2d 771, 774 (C.C.P.A. 1980). Under the rule of reason analysis, "[a]n evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor's story may be reached." *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) (citing *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993). The Federal Circuit has held that dated and witnessed notebooks of the inventor made in the course of research may be sufficient corroboration. *Berry v. Webb*, 412 F.2d 261, 267 (C.C.P.A. 1969). For example, such documents in addition to evidence that the inventor was part of a research team involved in developing the subject of

the patent may create a "cohesive web of corroborating evidence." *Hahn*, 892 F.2d at 1033 (citing *Berges v. Gottstein*, 618 F.2d 771 (C.C.P.A. 1980).

B. Collateral Estoppel

Monsanto argues that its prior reduction to practice is established independently by the collateral estoppel effect of the Delaware Judgment. The doctrine of collateral estoppel, otherwise known as issue preclusion, precludes a party from litigating an issue that has been previously decided in another action. *Disimone v. Browner*, 121 F.3d 1262, 1267 (9th Cir. 1997). The purpose of issue preclusion is to "conserve judicial resources, protect litigants from multiple lawsuits, and foster certainty and reliance in legal relations." *Id.* (citing *United States v. ITT Rayonier, Inc.*, 627 F.2d 996, 1000 (1980). A court may apply the doctrine sua sponte. *Id.* Collateral estoppel requires that "(1) the issue at stake must be identical to the one alleged in the prior litigation; (2) the issue must have been actually litigated in the prior litigation; (3) the determination of the issue in the prior litigation must have been a critical and necessary party of the judgment in the earlier action." *Clark v. Bear Stearns & Co., Inc.*, 966 F.2d 1318, 1320 (9th Cir. 1992) (citations omitted). "Similarity between the issues is not sufficient; collateral estoppel is applied only when the issues are identical." *Shapley v. Nevada Bd. of State Prison Com'rs.*, 766 F.2d 404, 408 (9th Cir. 1985) (citing *Parklane Hosiery Co. v. Shore*, 438 U.S. 322, 326 (1979)). Moreover, a Court is "allowed to draw necessary inferences from the prior adjudication in order to determine whether an issue was actually decided." *Disimone*, 121 F.3d at 1268 (quoting

Appendix D

Westinghouse Elec. Corp. v. General Circuit Breaker & Elec. Supply, Inc., 106 F.3d 894, 901 (9th Cir. 1997), *cert. denied*, 118 S.Ct. 155 (1997)).

The doctrine of collateral estoppel applies to determinations of patent invalidity. *Blonder-Tongue Lab. Inc. v. University of Illinois Foundation*, 402 U.S. 313, 349-50 (1971). In *Blonder-Tongue*, the Supreme Court held that the determination that a patent claim was invalid in one action precluded the patentee from asserting the patent claim in a second action. *Id. See also Huron Manufacturing Corp. v. CMI Corp.*, 201 U.S.P.Q. 111, 115 (D.S.D. 1978) (holding that the prior determination of invalidity of one patent estopped the patentee from asserting the validity of substantially similar claims in a different patent).

At the time this motion for summary judgment was initially brought, the crucial factors of collateral estoppel were whether the judgment is sufficiently final, and whether the issue of prior inventorship in this action is identical to that in the Delaware action.

1. Final Judgment

The Ninth Circuit requires a "sufficiently firm" final judgment before applying the doctrine of issue preclusion. *Robi v. Five Platters*, 838 F.2d 318, 326 (9th Cir. 1988) (citing *Luben Indus. v. United States*, 707 F.2d 1037, 1040 (9th Cir. 1988). Several factors are relevant to the determination of whether a final judgment is sufficiently firm, these include whether the: 1) parties were fully heard; 2) the court supported its decision with reasoned opinion, and

3) the decision was the "proper subject of appellate review." *Id.* (citations omitted). The Ninth Circuit has emphasized the importance of the availability of appellate review in determining the preclusive effect of a previous judgment. *See, e.g., Luben Indus. v. United States*, 707 F.2d 1037, 1040 (9th Cir. 1983) (holding that an interlocutory order was not "sufficiently firm" because it was not appealable).

However, the Ninth Circuit has also determined that while the pendency of post-trial motions following a jury verdict precludes an appeal, it does not necessarily bar the use of collateral estoppel. *Tripati v. Henman*, 857 F.2d 1366, 1367 (9th Cir. 1988) ("A pending Rule 59(c) motion similarly does not deprive a judgment of finality for res judicata purposes."). Under some circumstances, though, it may be preferable to allow the post-trial motions to be resolved prior to affording a judgment collateral estoppel effect. Therefore, on the record, the Court stayed the action pending the resolution of the Delaware case.

On September 8, 1999, the Delaware Court ruled on all of the pending post-trial motions. Hence, the Delaware judgment is now final for purposes of collateral estoppel, as well as for purposes of appeal. The second and related issue for collateral estoppel, however, is whether the issues in this case are sufficiently identical to the Delaware case such that the Delaware Judgment can be used by the Monsanto in this action.

2. Comparison of the Patents

Monsanto argues that a comparison of claims 1 and 11 of the '831 Patent to claims 1 and 7 of the '600 patent show that

the former claims are subsumed entirely within the latter. Monsanto provides a side-by-side comparison of claim 1 of the '831 Patent and claim 1 of the '600 Patent. (Def.'s Mem., Ex. J). After reviewing this comparison, it is apparent to the Court that claim 1 of the '600 patent includes all of the limitations of claim 1 of the '831 patent. The substantive differences between the patents are that claim 1 of the '600 patent includes the additional limitation requiring the removal of a number of codons having CG codon positions in positions II and III in a region between plant polyadenylation signals and the '600 patent adds two additional steps of inserting and maintaining, in addition to analyzing and modifying the steps. Thus, performing claim 1 of the '600 patent requires performance of every step of claim 1 of the '831 patent plus additional steps. As Monsanto argues, "[s]tated another way, if Monsanto reduced to practice claim 1 of the '600 Patent, it necessarily would have had to also reduce to practice claim 1 of the '831 Patent as well." (Def.'s Mem. at 4). Additionally, Mycogen relies on the same reduction to practice date in this action, September 8, 1988, as it did in the Delaware action. This is the date when it filed the parent application for all three patents. (Def.'s Mem., Ex. D). Therefore, a necessary component of the Delaware Judgment that Monsanto was the first to invent the claimed subject matter was a finding that it reduced to practice Claim 1 of the '831 patent before September 8, 1988.

Additionally, Monsanto persuasively argues that the same reasoning establishes Monsanto's prior reduction to practice of claim 11 of the '831 patent, because its limitations are encompassed entirely within those of claims 7 of the '600 patent. (Def's Mem., Ex. K). Indeed, all limitations of

claim 11 of the '831 patent are found in claim 7 of the '600 patent. Thus, the Delaware jury necessarily found that the Monsanto reduced the invention to practice denoted in claim 11 of the '831 patent before Mycogen.

Mycogen's objection to the applicability of collateral estoppel seems to arise from its different interpretation as to what issues exactly the Delaware judgment may preclude. It appears to be Monsanto's position that the Delaware Judgment only applies to the first element of their defense of invalidity; that they were the first to reduce the invention to practice. For example, within its table of contents Monsanto only mentions the Delaware judgment and collateral estoppel under point one for reduction. There is no discussion of collateral estoppel with respect to conception and reasonable diligence. (Def.'s Mem. at ii). Additionally, in its summary of the argument Monsanto states that, "[t]he Delaware Judgment collaterally estoppes Mycogen from relitigating the fact of Monsanto's prior reduction to practice of claims 1 and 11 of the '831 patent because the subject matter of these claims are encompassed entirely within certain claims of the '600 Patent already held anticipated by Monsanto's own work." (Def.'s Mem. at 2).

Mycogen, however takes the position that Monsanto relies on the doctrine of collateral estoppel to establish all three elements of its defense: reduction, conception and diligence. Mycogen's argument that collateral estoppel cannot apply centers on the differences between the two patents and how this could have lead the jury to conclude that Monsanto was the prior inventor because Mycogen could not show the second element, conception. (Pl's Mem. at 22). Specifically,

Appendix D

Mycogen claims that the '600 patent requires reducing the number of XCG codons in a region between plant polyadenylation signals or reducing the occurrences of the sequence of AATGAA. Claims 1 and 11 of the '831 patent do not include these limitations. Mycogen correctly explains that when it comes to the issue of **conception** this issue is critical. The Delaware jury could have concluded that Mycogen did not show that it removed the XCG codons or the sequence AATGAA. Mycogen explains that the Monsanto's focus was on the XCG and AATGAA elements at trial. For example, in their closing argument Monsanto stated:

> Now, ladies and gentlemen, the evidence that Mycogen advanced here comes nowhere close to this. They were looking for a solution in 1988 and the evidence is clear. There is another instruction that the Judge has given you and this one is a killer from (sic) Mycogen.
>
> 'Any conception must have all claim elements including alteration of the overall codon preference, together with the individual specific modification directed to the XCG's or the AATGAA sequence.'
>
> This is the single most important instruction in this case because Mycogen's evidence on this topic absolutely fails.'

(Pl.'s Mem., at 23 quoting Ex. 2 at 2437:3-16).

Hence, Mycogen correctly points out that the jury's finding relating to the second element of conception could have been

based solely on the claimed elements that do not exist in Claims 1 and 11 of the '831 patent. However, as Monsanto is not using issue preclusion for all three requirements for its defense of invalidity, Mycogen's argument is misplaced. Thus, the Court finds that collateral estoppel applies to the issue of reduction to practice. And, since the jury in Delaware concluded that Monsanto was the first to reduce to practice, that determination is binding here.

However, this determination does not end the inquiry. The second question is whether Monsanto has also independently shown that the Mycogen was not the first to conceive and/or was not diligent in reducing the invention to practice.

IV. Conception

A. Legal Standard

Priority of an invention "goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice." *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) (quoting *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993)). Given that collateral estoppel establishes that the Monsanto was the first to reduce to practice, Monsanto must now show that Mycogen cannot establish that it was the first to conceive of the invention and that it did not exercise reasonable diligence in reducing the invention to practice.

Appendix D

The test for conception is "whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention." *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). *See also Kridl v. Mccormick*, 105 F.3d 1446, 1449 (Fed. Cir. 1997) (quoting *Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985) (conception is the formation "in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice."). The formation must be "so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) (quoting *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994), *cert. denied*, 116 S.Ct. 771 (1996). Conception does not occur until the inventor can "describe his [her] invention with particularity." *Burroughs Wellcome*, 40 F.3d at 1228. An idea is definite and permanent "when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he [she] hopes to pursue." *Id.* An inventor, however, need not show that her or his invention will work for conception to be complete. *Id.* An inventor need only show that he or she had the idea; the discovery that the invention actually works is part of the reduction to practice analysis. *Id.*

As discussed above, when a party seeks to show conception through the testimony of an inventor, courts apply a rule of reason analysis. *Id.* (citing *Price v. Symsek*, 988 F.2d 1187 (Fed. Cir. 1993). Under this analysis, courts

evaluate all the pertinent evidence so that a sound determination of the credibility of the inventor's story may be reached." *Id.* The federal circuit does not require corroboration where a party seeks to prove conception through the use of physical exhibits. "The trier of fact can conclude for itself what documents show, aided by testimony as to what the exhibit would mean to one skilled in the art." *Id.* The parties seem to agree that the earliest date Mycogen needs to beat is October of 1986. (Def.'s Mem. at 19; Pl.'s Mem. at 16). Moreover, they do not seem to dispute the admissibility of corroborating evidence; rather, they argue that the evidence relied upon is not persuasive.

B. Monsanto's Argument

Monsanto raises two main points in support of its contention that Mycogen's scientists did not conceive of the invention prior to October of 1986. Namely, Monsanto asserts that: 1) the scientists did not understand what was causing the problem of the low expression of the native Bt gene in plants, 2) the scientists admitted that there is no one document that corroborates any conception of the specific idea to make a modified Bt gene that contains a greater number of plant conferred codons; and that nowhere in the minutes of the regular meetings of the Bt researchers is there any mention of the idea to rebuild the Bt gene to make it more plant-like or to make it have more preferred codons. Mycogen counters that: 1) while the scientists might not have known exactly what was causing the problem of low expression of the native Bt gene in plants, they did conceive of the solution to fix the problem of low expression; 2) while there is no one document that explicitly describes the claimed inventions, there is

a collection of documents that explicitly describe the claimed inventions; and 3) there is testimony of Mycogen ex-employees that corroborates its conception date. Interestingly, in its reply and at oral argument, Monsanto did not address Mycogen's arguments that there were a number of documents supporting the claimed invention and a number of employees that corroborate the conception date.

1. The Scientists' Understanding

Monsanto contends that the trial testimony of both Drs. Murray and Adang establish that they had no idea during 1985-87 why the native Bt gene was not expressing in plants. Monsanto points to the fact that Dr. Murray admitted in 1985 that she did not know anything more than that the Bt gene should be made more "plant like."

> Q: So at this point in time, in 1987, still it [Dr. Murray's lab notebook] says "to identify stretches where problems might exist." I mean it's still true in 1987 you didn't know what the problems were.
>
> A: I knew what the symptoms were and I had an invention that I thought would alleviate the symptoms but I did not know the underlying cause of the problem.
>
> Q: And you didn't find the cause of the problem, didn't have the idea for the problem until 1988; isn't that right?

A: I had the idea for the problem in 1985.

Q: You didn't know anything more than you though it [the Bt gene] should be plant-like?

A: That's correct.

(Def's Mem. at 9 quoting Ex. L at 326-27).

Monsanto further explains that Dr. Adang confirmed that the scientists did not know the reason for the poor expression of the Bt gene in 1985 and 1986, stating, "[w]e did not know at which of those specific sequence it was going off the track at." (Def.'s Mem. at 10 quoting Ex. L. at 429).

Monsanto argues that merely thinking that the Bt gene should be made more "plant like" does not establish a conception of claims 1 and 11 of the '831 Patent. Monsanto asserts that "Dr. Murray's admission that she had no idea how to fix the problem proves as a matter of law the absence of a conception of these claims which are, themselves, to methods for fixing the problem (sic)." (Def's Mem. at 9). This statement mischaracterizes her testimony. Dr. Murray testified that while she did not know what caused the problem, she had an invention that she thought would alleviate the symptoms of the problem. Indeed, as Mycogen asserts,

> Monsanto's argument misses the point. Dr. Murray (and Dr. Adang) testified that they had conceived **the solution** to fixing the problem of the low expression of native Bt genes in plants, a solution which is now reflected in the claims of the

> '831 Patent. The fact that Dr. Murray may not have understood exactly what was causing the problem in the first place is irrelevant in light of the fact that she conceived **the solution to the problem**

(Pl's Mem. at 16).

For example, in her cross-examination, Dr. Murray stated that various experiments she performed "substantiated my original idea I had in 1985 that I should continue to rebuild the entire gene as opposed to just trying to do a small portion of the gene." (Ex. L. at 331). It appears that at least part of Monsanto's strategy when cross-examining Ms. Murray was to get her to admit that she did not have the idea in 1985 to take out the XCG codon. Rather, she had the broader idea of plant favored codons. Monsanto's asked, "You do not have the idea, the definite and permanent idea in 1985 that you were going to sit down, analyze the Bt gene, look at the coding sequence and take out an XCG codon. You did not have that idea in 1985, did you, Dr. Murray?" Dr. Murray answered, "I had a broader idea. That is, a subset of the original idea." (Def.'s Ex. L. at 304). The focus of the testimony provided by Monsanto really centered around reducing the number of XCG codons and reducing the occurrences of the sequence AATGAA. It is the Court's understanding that both of these claims are not part of the '831 patent.

Moreover, as Mycogen points out, Drs. Murray and Adang testified that they conceived of the inventions claimed in claims 1 and 11 of the '831 Patent in November of 1985. For example, Dr. Adang testified that in November of 1985, he had the idea of how to build a Bt gene that would be better

expressed in plants based on improving the codon frequency to took more like plant genes. (Pl.'s Ex. 10 at 8:13-13:20). He testified that he and Dr. Murray had a series of discussions around November of 1985, concerning modifying a Bt gene by increasing the number of preferred codons to improve expression. (Pl.'s Ex. 10 at 11:1-13:20; Ex. 11 at 216:17-218:2). When Dr. Murray was asked whether in November of 1985, she had the specific idea for modifying the coding sequence of a Bt gene to result in a greater number of codons preferred by the intended plant host, her answer was, "[i]n November of 1985, I think I did have that specific idea." (Pl.'s Ex. 11 at 227:22). Both she and Dr. Adang testified that in November of 1985, they explored modifying the Bt gene to yield a modified sequence that contained either a greater number of plant-preferred codons or had a frequency of codon usage that more closely resembled the frequency of codon usage of the intended plant. (Pl.'s Ex. 11 at 227:22-231:5; Ex. 10 at 8:13-11:12).

This testimony standing alone shows that the scientists did understand the nature of their invention in 1985. However, for this testimony to be enough to prevent summary judgment, it must be corroborated. Corroborating evidence is required when a party seeks to show conception by the oral testimony of the inventor. *Kridl*, 105 F.3d at 1449-50; *Mahurkar*, 79 F.3d at 1577. The requirement of corroboration reflects a concern that "inventors testifying in patent infringement cases would be tempted to remember facts favorable to their case by the lure of protecting their patent or defeating another's patent." *Mahurkar*, 79 F.3d at 1577.

Appendix D

2. Documentation

Monsanto argues that there is "no credible evidence" to corroborate any conception by Mycogen of the specific idea of making a modified Bt gene which contains a greater number of plant preferred codons. (Def.'s Mem. at 7). Monsanto points to the fact that at trial Dr. Murray admitted that she did not write down the basic concept of how to "fix" the plant and make it express the Bt toxin. (Def.'s Ex. L at 310). Defense counsel asked, "Dr. Murray, the first time you ever wrote down the very — any kernel of an idea that you were going to do this, actually have had this idea, was in August of 1987; isn't that right?" Dr. Murray answered, "Yes." (Def.'s Ex. L. at 310). Monsanto also points to Dr. Adang's testimony where he admitted that during 1985-1986, there is no one document that says Mycogen was going to use preferred codons, and there was no document that says the scientists wanted to make the Bt gene more plant like. (Def.'s Ex. L. at 430-431). Monsanto asserts that the absence of documentation is particularly telling in light of the policy of their employer that any significant research ideas be recorded in their lab notebooks. (Def's Mem. at 8 citing Ex. L at 309-09, and 434-35). Additionally, Monsanto points to the fact that Dr. Adang admitted at trial that nowhere in the regular minutes of the meetings of the Bt researchers, or, for that matter, in any scientists' lab book, is there any mention of the idea to rebuild the Bt gene to make it more plant-like or make it have preferred codons. (Def.'s Ex. L at 433-34). The first document that says anything about preferred codons is an August 27, 1987 lab notebook entry where Dr. Murray writes, "the general idea is we should change the codon sequence of the Bt gene to make it more plant-like." (Def.'s Ex. L. at 317-18).

This is followed four days later by the minutes for the Bt group meeting on September 1, 1987, at which codon usage was discussed. The minutes state simply, "codon usage?" (Def.'s Ex. M. at 580).

Mycogen counters that Monsanto's characterization of Dr. Adang's trial testimony is misleading. "While Dr. Adang did testify that there was not one document which explicitly described the claimed inventions, he also testified that there was a collection of documents which, taken as a group, corroborated his and Dr. Murray's conception." (Pl.'s Mem. at 16). For example,

> Q: Now, Dr. Adang, when you come up with this idea in the fall of 1985, did you write down this idea?
>
> A: I have not found any documents that explicitly state all this, the entire context of this idea. What I have found, and what we talked about here, is there is this evidence saying that we knew the Bt RNA was truncated. We knew the Bt gene was At-rich. We knew that the Bt genes preferred At codons. We knew we were getting some type of termination of transcription. And we knew how to fix it, through mutagenesis or building up stretches of the whole gene.
>
> Q: Do you believe that you have any documents that show that you and Dr. Murray did come up with this ideal in November of 1985?

> A: I think all those documents collectively that I just mentioned, the RNA analysis [Exs. 25-26], the computer searches [Exs. 27-32] and the AT-richness [Ex. 33], the UCLA abstract (Ex. 34], they all support, corroborate this invention of Dr. Murray's and mine.

(Pl.'s Mem. at 16 quoting Ex. 2 at 1729:3-20, 1752:15-20).

Mycogen does not respond to or counter the fact that reference to codon usage was not found in the scientists' lab notebooks or minutes of the meetings. Perhaps, standing on its own, this one reference to various documents would not be enough to amount to a dispute of material fact, i.e., it would not be enough for corroboration, but this fact, taken with the testimony of ex-employees, creates disputed issues of fact.

3. Testimony of Ex-Employees

Mycogen argues that Monsanto ignores the testimony of various ex-employees all of whom provide oral testimony corroborating Mycogen's conception date. As previously discussed, corroboration by witness testimony is appropriate. *Kridl*, 105 F.3d at 1446. Mycogen points to the testimony of ex-employees.

First, Dr. Romero-Severson testified that from 1985, through March of 1986, he and Dr. Murray had offices across from each other and she often discussed the Bt project with him. Specifically, "she told me that the problem was that the gene needed to be fixed, and she would say that over and over, and that any other method of research was simply futile

until you did that. So she said what you got to do is take the gene, and resynthesize it, so that the codon usage looks plant-like, so that the plant will then recognize it and make a full length transfer." (Pl.'s Mem., Ex. 2 at 1845:16-22; *See also* Ex. 12 at 74:23-93:01, 143:10-145:2 & 183:18-184:3).

Second, Ms. Carolyn Stock testified that in the fall of 1985, she had continuous conversations with Dr. Murray about the Bt gene, and Dr. Murray told her that one way to solve the problem with the gene expression was to change the Bt gene to mimic the codon usage in the plant. (Pl.'s Ex. 13 at 48:4-52:13, 58:8-23, 62:13-63:24, 66:11-72:5 & 82:25-84:13, 128:9-129:15).

Third, Dr. V. Sekar testified that early in 1986, Dr. Murray told him that she believed that the coding region of the native Bt gene needed to be modified to be more plant-like to have the Bt gene express in plants. (Pl.'s Ex. 14 at 48:10-50:14).

While the fact that the claimed conception did not appear in one document may not appear very credible to this Court, it is not for this Court to determine. Credibility is a proper question for the jury. Given the conflicting inferences possible from Dr. Murray's testimony, as well as the collective documents referred to by Dr. Adang and the testimony of the ex-employees, it appears there is a dispute of material fact as to the date Mycogen conceived of the claimed invention.

V. Reasonable Diligence

Even though there is a triable issue concerning whether Mycogen was the first to conceive, to survive summary

judgment there must also be a triable issue of fact concerning whether Mycogen was diligent in reducing the conception to practice. Under 35 U.S.C. § 102(g), a party will not be afforded priority of inventorship if it was the last to reduce to practice unless it exercised reasonable diligence in reducing the claimed invention to practice. 35 U.S.C. § 102(g). This public policy encourages the introduction of valuable technology into the public forum at the earliest possible date. The first question is how can a party be diligent. "It is well settled that, to satisfy the 'reasonable diligence' requirement of 35 U.S.C. § 102(g) the work relied on must ordinarily be directly related to reduction to practice of the invention of the counts in issue." *Naber v. Cricchi*, 567 F.2d 382, 385 (C.C.P.A. 1978), *cert. denied*, 439 U.S. 826 (1978).

The second issue is when a party must be diligent. The diligence must extend continuously from just before the Defendant's conception until the Plaintiff's reduction to practice. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996); *Keizer v. Bradley*, 270 F.2d 396, 397 (C.C.P.A. 1959).

A. How to be Diligent

The parties dispute on this issue centers around whether electroporation and S-1 mapping experiments performed by Dr. Murray and reviewed by Dr. Adang from 1985-1987 were necessary to Mycogen's reduction to practice of claims 1 and 11 of the '831 Patent. Mycogen's claim for diligence turns on a series of experiments, known as RNA mapping experiments and electroporation experiments, which allowed scientists to identify the regions of the native Bt gene that

caused the low expression and allowed the scientists to develop a codon modification. (Pl's Ex. 2 at 1729:21-1733:22). Mycogen contends that the scientists "thought it would be faster and cheaper to reduce the invention to practice by finding a specific region of the native Bt gene to modify according to the frequency or greater number concepts, instead of modifying or rebuilding the entire native Bt gene." (Pl.'s Mem. at 18). But, in some ways, Mycogen seems to admit that the patent is not about partial modification, because it goes on to state, "when they were unable to locate such a region by 1988, they decided to rebuild the entire gene." (Pl.'s Mem. at 18). Mycogen relies on the testimony of Dr. Adang who explained in relevant part:

> Q: After you and Dr. Murray conceived this idea in November of 1985, how did you proceed to implement the idea?
>
> A: Well, we discussed how to approach this problem, how to go about fixing the Bt gene by replacing these At-rich codons with plant-preferred codons. We thought that the quickest way to change the Bt gene so it was highly expressed was to go into the gene and to find those stretches of the Bt gene that were causing the greatest problems for this — greatest problems causing lower expression. So we designed a series of experiments to try to identify the worst regions of the Bt gene, that we could then go back and fix, putting in plant-preferred codons.

Appendix D

Q: What were these experiments?

A: These were a series of experiments. Their names are — there are a couple of types. There is mapping, RNA mapping experiments. What this means is that we were going to define the exact ends of the Bt RNA that was found in these transgenic plants. We knew that if we could map those precise ends, that we would have the degradation or termination signals nearby. So we had mapping experiments. These deleting experiments, they were designed to cut back portions of the Bt gene, cut it back to a point then that when we put it into our plant cells, that Bt RNA would be stable. We could then go back and fix that region of the Bt gene. We also set up a series of what we called electroporation experiments. It takes a while to do plant transformation experiments. We felt if we could develop in-house at Agrigenetics an electroporation system and we did develop this, we would have a way to test modified Bt constructs very rapidly. So we did that. Also then, along the line of this invention, I continued my analysis of the Bt gene and the computer searches to pinpoint each of the problem areas that we can fix in the gene.

Q: Dr. Adang, the mapping experiments you just described, the deletion experiments, and the computer searches, and the computer searches, did those involve the native Bt gene?

A: They did involve the native Bt gene.

Q: If that is so how do they relate to your invention?

A: How they relate to the invention is that by identifying the regions of the native Bt gene that were the worst that caused this instability. this termination, this low expression, that we could then go back and, using this and for codon modification changing from AT-rich Bt-type codons to Bt-rich, plant-type codons, we could then have a stable rebuilt gene that was highly expressed in plants.

. . . .

Q: Why did you make the decision to try to find specific regions of the gene to change, instead of just rebuilding the whole gene in '85?

A: Well, first of all, we wanted to accomplish the task of getting a highly-expressed gene as rapidly as we could. And the technology for building genes in 1985 was very, very primitive, if you will. And we could have done it but it would have taken a long while and it would have been very expensive. We thought if we could quickly go in, identify the problem regions, we could then fix it and have a rebuilt Bt gene that were highly expressed.

Appendix D

Q: Was there a time when Agrigenetics decided to actually rebuild the entire gene?

A: Yes, there was.

Q: When was that?

A: This was in January of 1988.

Q: Why was that decision made at that time?

A: Well, I presented the argument to the group and to a number of people at our company that the technology was really at hand for building the full-length Bt gene. We had hoped that this path of finding the worst part of a Bt gene would be the rapid route. And it indicated to us there were a lot of problem areas with the Bt gene. So we knew we had to fix — we felt we had to fix a number of areas of the Bt gene, and we also felt that the technology was now available that my team at Agrigenetics could build the gene that would be expressed in plants.

(Pl's. Ex. 2 at 1729:21-1733:22).

Distilled to its essence, Dr. Adang's testimony is important in several respects. First it suggests that the experiments were related to modifying a portion of the Bt gene; that is, looking for where in the DNA sequence they should manipulate the codons. Second, this testimony establishes that such

experiments were not relevant to the ultimate patent because they decided that there was no one particular position they should or could change, rather they needed to rebuild the whole gene. Third, as the Monsanto points out, Dr. Adang's testimony is pretty damaging in that he admits that the reason they looked for problem areas instead of figuring out how to rebuild the entire gene was because it would be less expensive and less difficult. The reasonable diligence standard balances "the interest in rewarding and encouraging invention with the public's interest in the earliest possible disclosure of innovation. *Griffith v. Kanamaru*, 816 F.2d 624, 626 (Fed. Cir. 1987). Public policy favors the early disclosures of inventions and this underlies the requirement for "reasonable diligence." As a consequence, a patent rewards people for taking the plunge into expensive and/or difficult experiments. Allowing scientists to put aside the difficult approach to try the easier approach, bur then still get a patent for the difficult approach, seems contrary to such public policy.

The Court is persuaded by the Monsanto's argument that these experiments by Mycogen were only relevant to find a particular problem region of the Bt gene and that such research is not related to the claimed invention. Monsanto points to the claims of the '831 patent and asserts that nowhere in the claims is there any direct mention of problem regions, rather the claims discuss modifying the entire gene without limitation to any problem region.

First, as described above, Dr. Adang's testimony does suggest that the experiments were not related to the ultimate invention. Indeed, Dr. Adang is later asked:

Appendix D

Q: Did you know in 1985 what the solution was to fixing the Bt gene to make it express better in plants?

A: Yes.

Q: What did you know in 1985?

A: In 1985, we knew that the Bt gene was At-rich. We knew that the Bt gene had A's and T's at the third codon position. We knew they had polyadenylation sites. We knew they were not like plant genes and we knew — we knew about plant codons so we knew how to make substitutions and had decided how to do it to rebuild a Bt gene.

Q: Now do you believe that you had the solution to fixing the Bt gene, even though you did not know where it was going off track, to use Mr. Lynch's language?

A: Yes, I do believe that.

Q: Why do you believe that?

A: Because our method of changing to plant preferred codons would have worked. We chose the approach to find where it was going off track as quick — as the quickest route. We thought it would save us time, but our original method of using plant preferred codons, we didn't know where it was off track."

(Def.'s Mem., Ex. L. at 438:8-439:4).

As Monsanto asserts, this testimony illustrates that the research efforts to find a specific problem region were not necessary to the original idea of inserting plant preferred codons. Rather, this approach was taken because it would be quicker and cheaper.

Second, Monsanto asserts that Dr. Murray admits that the purpose of the test was to determine a specific region in the gene in which these changes should be made and that she could have redesigned the entire Bt gene in 1985 which is claimed in 1 and 11 without any of these experiments. (Def.'s Mem. Ex. L at 324-325). Dr. Murray testified that:

> Q: And isn't it a fact, Dr. Murray, that you didn't get any results from any of these experiments that told you how to change the codon usage of the Bt gene?
>
> A: No.
>
> Q: You didn't get any results from them that you used in designing a Bt gene did you?
>
> A: Yes.
>
> Q: The results weren't conclusive, were they, Dr. Murray.
>
> A: The results indicated that no matter how small a gene, a fragment of a gene that I put into plants I was still unable to detect a stable RNA transcript. And that indicated to me that we

should rebuild the entire gene, as opposed to just trying to fix a section of the gene, which had been my original premise behind doing the RNA mapping experiments and the fact that I could not map the RNA that was unstable indicated to me that I should rebuild the gene, because the RNA was unstable.

Defense counsel then questioned her with respect to her deposition testimony rereading his question.

Q: I said: "So the experiments that you're talking about you used to try to narrow down the possibilities of what needed to be changed in the Bt gene sequences. Is that what you're telling me?" And you said, "Yes. And for other reasons." And I asked you the question: "Isn't it a fact, Dr. Murray, that none of those experiments that you described to me told you which codons made the Bt gene more plant-like?" You said: "No. Those experiments did not tell me which genes made the Bt gene more plant-like." And I asked you, "you mean which codons?" And you said: "No. Which codons made the Bt gene more plant-like." That was not their purpose?

A: That's correct.

. . . .

Q: These experiments told you nothing more, Dr. Murray, than you had short segments of RNA. That's all they told you.

A: That's not correct.

Q: These experiments, Dr. Murray, didn't tell you I should design a synthetic Bt gene and remove XCG codons, did they?

A: That was not correct. These experiments told me the results they told me. They were x-ray films, and then I interpreted those results, and as an inventor, I felt they substantiated my original idea I had in 1985 that I should continue to rebuild the entire gene, as opposed to just trying to do a small portion of the gene.

(Def.'s Mem., Ex. L at 328:20-331:24).

In this testimony, Dr. Murray admitted that these experiments were not necessary to determine which codons should be changed to make the Bt more plant-like. Rather, they told her that it would not be possible to get the Bt toxin to express itself in plants by only altering a small portion of the gene. Additionally, she stated in her testimony that these experiments substantiated her original idea that the whole gene needed to be rebuilt, since they could not focus on just a portion.

It appears that Dr. Murray saw two possibilities: 1) fix the whole gene, 2) fix the most unstable part of the gene.

Appendix D

The experiments from 1985-1987 are specific to the second possibility. Once the scientists realized that the second possibility would not work, they went back to the first possibility which is the subject of the patent. Monsanto cites to a very old case which provides some insight. *Fageol v. Midboe*, 56 F.2d 867 (C.C.P.A. 1932). In *Fageol*, the patentee conceived of a dual axle drive to be used in building a large size-wheel bus, but instead of building the bus or filing a patent application, his employer chose to experiment with other shaft designs for two years. *Id.* at 868-69. Two years later he decided to patent the original design. The court found that the work on the unrelated technology did not excuse the period of inactivity directed to the invention in question and awarded priority to another patent who reduced the same invention to practice first. The Court held,

> Even conceding that [the patentee] was the first to conceive, he should not be permitted to lay his conception aside, take up, and experiment with, many other mechanical problems and devices, and then be permitted to defeat one who enters the field and reduces the invention to practice while he was experimenting with such other devices. This doctrine based on sound reasoning, has been repeatedly announced by the courts.

Id. at 868-69 (citations omitted).

The present case seems similar. It appears that Mycogen laid the conception of rebuilding the whole Bt gene aside to experiment with other solutions, i.e. only fixing a problem area. Mycogen does not address this argument. As a final

point, it is not clear to the Court that the inventor's claim that these tests were necessary and related is sufficient, because there is no corroboration. As with conception and reduction, the same rule of reason requiring corroboration applies. *Gould v. Schalow*, 363 F.2d 908, 919 (C.C.P.A. 1966).

Hence, no material question of fact exists as to whether Mycogen was diligent in reducing its invention to practice. By working on unrelated experiments, Mycogen was clearly not diligent. The second question is whether Mycogen was not diligent during the time period in question.

B. When to be Diligent

While the parties agree that Mycogen reduced its invention to practice on September 9, 1988, there is some disagreement with respect to Monsanto's conception date. As Monsanto points out in its reply, Mycogen does not contest that Monsanto had the complete idea to solve the Bt expression problem by creating a synthetic Bt gene which was modified to contain a greater number of codons preferred by plants. Rather, Mycogen argues that Monsanto cannot corroborate a conception of the elements claimed in the '831 patent. In other words, Monsanto cannot show that it actually understood and conceived the claims in the '831 patent which Mycogen terms the "frequency and greater number concepts."

1. Mycogen's Conception

Mycogen cannot dispute that by October of 1986, Monsanto had the idea to solve the Bt expression problem by creating a synthetic Bt gene modified to contain a greater

number of codons preferred by the plants. Dr. Perlak testified that, in October 30, 1986, they documented in their lab notebooks the idea to totally synthesize the Bt toxin gene using codons that were the most plant preferred. (Def.'s Mem. Ex. L at 345-353). Dr. Fischhoff further explained that he and Dr. Perlak worked in earnest on the Bt gene in 1985 and 1986, and on October 30, 1986, he memorialized all of their thoughts on paper and drafted the final version of a memo, "what we could call now a conception document, that outlined the problem, the issues in the Bt genes, what we had seen before, what the symptoms were, then our ideas for the solution namely resynthesizing, come up with a synthetic Bt gene that would fix all those problems." (Def.'s Mem. Ex. L at 414:17-22). In short, as he documented in his memo, the solution was resynthesizing: "You take out things that you think are the cause of the problems and you have to replace them with something. What you replace them with are codons that are plant-like." (Def.'s Mem., Ex. L at 418:20-24). When asked why they claimed October 30 as the conception date even though they worked on the problem at an earlier time Dr. Fischhoff replied, "[w]ell, October 30 is really the date when we decided that we had enough ideas and knew the solution to the problem to really set it down on a piece of paper that we would be committed to as our approach to the solution. And that was important to us to actually write it and document it and then paste it into our laboratory notebooks." (Def.'s Mem., Ex. L at 415:18-24).

2. Corroboration

Monsanto cites to various documents and witness testimony for corroboration. First, in an internal Monsanto

report actually dated February 14, 1984, there are documented test results which "show that these nuclear genes from dicotyledonous plants seldom use the codon families CGX, XCG, and XUA. (Def's Mem., Ex. N). The report goes on to document that:

> Examination of the frequency with which all codons are used by an organism to make its protein allows us to identify these codon usage biases, if they exist, and which will possible allow us to use this information to obtain higher expression of desired proteins by either judicious choice of the sources of or by manipulation of the coding sequences.

(Def.'s Mem. Ex. N. at 604).

Moreover, the report contains codon usage tables that set forth the preferred codons of various types of plants. As Monsanto explains, "this document proves that Monsanto had completed these codon tables, the essential tool to practicing claims 1 and 11, more than three years before Dr. Murray began compiling her own codon tables in August of 1987." (Def.'s Mem. at 10).

Second, Monsanto cites the memorandum referred to by Drs. Perlak and Fischhoff which they claimed to have written on October 30, 1986. The Memorandum was pasted in Dr. Fischhoff's notebook on December 12, 1986. This document discusses eliminating the AT-rich codons that are disfavored by plants as a way to enhance the expression of the Bt gene. (Def.'s Mem. Ex. O). The document also suggests "mutagenesis"

to "change individual nucleotides or groups of nucleotides but would not alter the amino acid sequence of the protein produced." *Id.* Hence, as Monsanto suggests this document corroborates the conception of modifying the Bt gene to contain a greater number of codons preferred by plants which is the concept of claims 1 and 11 of the '831 patent.

Third, Monsanto cites various trial testimony. First, they cite Dr. Steven Rogers who testified that beginning in 1983 scientists at Monsanto began looking at what factors might affect the ability of certain genes to be expressed in plants. One of the concepts was that there was a preference for certain codons rather than random codons. The scientists generated tables of codon usage, meaning tables documenting which certain codons were used in particular organisms. (Def.'s Mem., Ex. L at 399:5-400:8). He explained that around mid-year David Fischhoff transferred into his group and began reporting to him regarding the project to increase the production of Bt protein in plants. He explained that in September or October of 1986, he and Fischhoff had a meeting and discussed how the Bt genes had a particular bias against the A and T in the DNA sequence, and how certain sequences needed to be removed and replaced with other less AT-rich sequences. Dr. Rogers explained that they wanted to make the same protein in the ends so they used guidelines and maps for which codons would be used "because we knew what the plants themselves preferred to use when they were making proteins." (Def.'s Mem., Ex. L at 403:8-10).

As a result of these meetings, Dr. Rogers explained that Dr. Fischhoff's "progress goals document" (introduced in the Delaware trial) for 1987, written in 1986, cited the specific

goal of synthesizing a modified Bt gene with different codon usage to solve the Bt gene expression problem. (Def.'s Mem. Ex. L at 405-410). Moreover, Dr. Klee testified that as early as summer and into the fall of 1986, he had conversations with Dr. Perlak about his intent to design a synthetic Bt gene. (Def.'s Mem., Ex. L. at 375-376). He testified that his understanding of the method or approach that Dr. Perlak adopted was to remove the sequences that destabilized the genes, remove the polyadenylation signals, and "move the codon usage towards what the plants use as opposed to what the bacteria sequence was." (Def.'s Mem., Ex. L. at 379:20-380:6). Additionally, he testified that in the year-end summary for his group, which summarized the results up through December of 1986, they discussed restructuring segments of the gene while still maintaining the toxin protein sequence. (Def.'s Mem., Ex. L at 377-78). Hence, there is sufficient corroboration that Monsanto conceived of claims 1 and 11 of the '831 patent by October 30, 1986.

Therefore, Mycogen is required to have been diligent from Monsanto's conception, October 30, 1986, until Mycogen reduced the invention to practice on September 9. 1988. *Mahurkar*, 79 F.3d at 1578. Since, as previously discussed, Mycogen experimented an other possibilities than the patented technique during this time period. Mycogen was not diligent.

3. The Frequency and Greater Number Concepts

The essence of Mycogen's argument is that none of these documents or witness testimony contains any mention of the concepts claimed in the '831 patent. Mycogen references its

earlier argument (at pgs. 7-15) regarding reduction to practice to state that Monsanto did not conceive of the frequency and greater number concepts. In short, the frequency concept is found in claim eleven which reads a method of . . . "modifying a portion" of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed. Def.'s Mem., Ex. A, col. 38, claim 11).

In other words, the goal is to change the frequency of use of the synonymous codons, so they appear in a distribution that more closely resembles the distribution of those same codons in the plant hosts. Mycogen also contends that claim 1 requires a greater number limitation since it states in relevant part, "modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons, preferred by the intended plant host than did said coding sequence." (Def.'s Mem., Ex. A, col. 38, claim 1).

Judge McKelvie held a Markman hearing and after considering extrinsic evidence held that this claim for a greater number limitation requires nothing different than the greater frequency limitation. Hence, with this interpretation of the claims, Monsanto must have understood that the newly-created synthetic gene has a higher number of codons, whose frequency in the native Bt was lower, such that the synthetic gene has an overall distribution of codons usage that is closer to the intended plant. (Pl.'s Mem. Ex. 1 at 28-29). Mycogen disputed this interpretation but seems to admit that it would be controlling here. Additionally, Judge McKelvie's interpretation of the claims must be applied here under the doctrine of collateral estoppel.

Appendix D

To support its claim that Monsanto did not understand that the frequency of the codons must be altered, Mycogen marches through a litany of testimony for various witnesses. As Monsanto points out, it does seem nonsensical to assert that Monsanto did not appreciate the invention, given that they produced a synthetic gene that successfully produced toxins because of codon alteration. In short, they produced the product claimed by the patent. The fact that they were able to do so indicates by implication that they conceived of the utility; in other words, they understood the invention. *See, e.g., Rey-Bellet*, 493 F.2d 1380, 1385 (C.C.P.A. 1974). In *Rey-Bellet* the Court explained that to conceive of an invention you must understand its utility. The court held that the evidence sufficiently corroborated conception of the invention. The key factor was the structural similarity of the compounds of the invention to the prior art compounds having a known use; this indicated by implication the conceived utility. *Id.* at 1385-86. A similar finding is warranted here. Monsanto asserts that Mycogen "admits that Monsanto's reduction to practice of a synthetic Bt gene resulted in the elimination of codons that are rarely used by the plant. This is equivalent to saying that the gene is made more plant like." (Def.'s Reply at 5). Hence, they must have conceived of the utility. Monsanto need not recognize, "the invention in the same terms as those recited in the count [of the patent claims]. The invention is not the language of the count but the subject matter thereby defined." *Silverstri v. Grant*, 496 F.3d 593, 599 (C.C.P.A. 1974). The above cited testimony of the Doctors establishes that they knew the key was changing the codons to make the Bt gene more plant-like. It appears to the Court that using more plant preferred codons is what the claims of the patent address.

Appendix D

VI. Abandonment

Assuming that there are no triable issues of fact with respect to prior inventorship, Mycogen can still invalidate a conclusion that Monsanto is the prior inventor by showing that Monsanto suppressed, concealed or abandoned the invention. The burden of proof is on Mycogen. *Cochran v. Kresock*, 530 F.2d 385, 392 (C.C.P.A. 1976); *Lutzker v. Flex*, 843 F.2d 1364, 1366 (Fed. Cir. 1988) ("The second party to conceive and reduce the same invention to practice will be awarded priority of invention if he [she] can show that the first party to reduce to practice abandoned, suppressed or concealed."). Section 102(g) requires that the prior invention has not, "abandoned, suppressed or concealed" the invention. 35 U.S.C. § 102(g). Suppression or concealment is a question of law. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1567 (Fed. Cir. 1996) (citing *Brokaw v. Vogel*, 429 F.2d 476, 480 (C.C.P.A. 1970). There are two types of suppression, cases where the inventor deliberately suppresses or conceals the invention, and cases where a legal inference of suppression or concealment is made as a result of a long delay in filing a patent application.

As a preliminary matter, Monsanto mentions in passing that suppression was raised by Mycogen in the Delaware trial and was necessarily rejected by the jury. Indeed, the Jury was instructed in instruction number 4.2.7a. that they could not find Monsanto was the prior inventor unless they proved by clear and convincing evidence that they did not abandon, suppress or conceal the invention. As the '831 Patent is subsumed entirely in the patents in the Delaware case and because the jury found that Monsanto was the prior inventor,

they necessarily decided that Monsanto did not abandon, suppress, or conceal the '831 invention. Thus, collateral estoppel bars the relitigation of this issue.

Even assuming that collateral estoppel is inapplicable, there is no evidence of intentional suppression. Intentional suppression requires more than a passage of time. "It requires evidence that the inventor intentionally delayed filing in order to prolong the period during which the invention is maintained in secret." *Id.* Mycogen argues that Monsanto has presented no evidence that it revealed the concepts to the public in its patent application. Its argument is cursory and conclusory and does not create disputed facts.

Second, a delay in filing a patent application can be shown by spurring. "Evidence that a first inventor was spurred to disclose by the activities of a second inventor has always been an important factor in priority determinations because it creates an inference that, but for the efforts of the second inventor, the public would never have gained knowledge of [the invention]." *Id.* at 1567 (quoting *Brokaw v. Vogel*, 429 F.2d 476, 480 (C.C.P.A. 1970). Mycogen argues in two sentences that the evidence is sufficient to support spurring because it shows that Monsanto did not put a codon usage table in its draft patent application until after it saw Mycogen's patent application. Thus, Mycogen's argument for spurring is not that the Monsanto was spurred to work on the patent application, but instead that it was spurred to include a particular aspect in its application. This does not seem like a proper application of the doctrine. The Federal Circuit held in *Fujikawa* that because it was uncontroverted that one inventor was already working on the draft application of

a patent before learning of another's patent, no spurring could be found. *Fujikawa*, 93 F.3d at 1568. Monsanto asserts "that it is uncontested that Monsanto was already working on a draft of its application prior to the time it allegedly saw the Mycogen application." (Def.'s Reply at 9). This appears uncontested as Mycogen asserts that Monsanto did not put a codon usage table in its patent application drafts of September 19, 1988 or October 5, 1988, but they appeared after they saw Mycogen's patent in December of 1988. Furthermore, as explained at oral argument, it is uncontroverted that Monsanto scientists were using these codon charts as early as 1984. Accordingly, the Court does not see how spurring is relevant.

VII. Prior Inventorship of Claims 3, 4, & 8

Monsanto argues that claims 3, 4, and 8, of the patent, which all depend on claim one, are also invalid under § 102(g) because Mycogen did not conceive of claim 1 first, or alternatively, was not diligent in reducing claim 1 to practice. Since the Court has found that there are no material facts in dispute regarding who was first to reduce to practice or diligence, these claims are invalid under 35 U.S.C. § 102(g).

VIII. Obviousness of Dependent Claims

Monsanto also argues that a determination that it invented claims 1 and 11 first also invalidates the remaining dependent claims under § 103. Monsanto reasons that these Dependent claims merely reflect what was known in the prior art about specific sequences disfavored by plants, such that anyone skilled in the art would have known to remove the sequences

specified in the dependents claims. However, this argument seems to turn on a finding that they were in fact the first to invent; this requires reduction, conception and diligence. Accordingly, since there are no material facts in dispute regarding two of the three factors, summary judgment is appropriate. The Court, therefore, GRANTS Monsanto's motion for summary judgment under § 103.

IX. CONCLUSION

For the reasons set forth above, this Court LIFTS the STAY and GRANTS Defendant's motion for summary judgment of invalidity under 35 U.S.C. §§ 102(g) and 103, and DENIES as MOOT Defendant's motion for summary judgment under 35 U.S.C. § 112. The Clerk of the Court is instructed to Close the file on this case.

IT IS SO ORDERED.

DATED: November 10, 1999

s/ Napoleon A. Jones, Jr.
NAPOLEON A. JONES, JR.
United States District Judge

APPENDIX E — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA RE MOTIONS FOR SUMMARY JUDGMENT DATED AND FILED AUGUST 15, 1996

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Case No. 95-0653-J (LSP)

MYCOGEN PLANT SCIENCE, INCORPORATED, a Delaware corporation, and AGRIGENETICS, INCORPORATED, a Delaware corporation,

Plaintiffs,

v.

MONSANTO COMPANY, a Delaware corporation,

Defendant.

ORDER DENYING MOTION FOR SUMMARY JUDGMENT OF VALIDITY; DENYING MOTION FOR SUMMARY JUDGMENT RE: INTERPRETATION OF 35 U.S.C. § 271(g); GRANTING MOTION FOR SUMMARY JUDGMENT ON CLAIM CONSTRUCTION

This action is before the court on three motions (1) Mycogen's motion for summary judgment of validity of their patent; (2) Mycogen's motion for summary judgment re: Interpretation of 35 U.S.C. § 271(g) and (3) Monsanto's motion for summary judgment on claim construction. For the reasons set forth below, the court denies Mycogen's motions and grants Monsanto's motion.

Appendix E

Mycogen's Motion for Summary Judgment of Validity

This litigation deals with whether Monsanto has infringed or is infringing Mycogen's process and product patent claims involving a method for genetically engineering plants to be toxic to insects and two specific genetic sequences produced through that engineering. The focus of this litigation so far has been Monsanto's argument that Mycogen's process patent claims cannot cover any development done before the issuance of the patent. The court has ruled that a process performed before the patent issued would not infringe the process claim is Mycogen's patent. Monsanto has further maintained (1) that it has done nothing since the issurance of the patent that would infringe the process claims and (2) the plants that it is commercializing are not covered by the product claims in Mycogen's patent because the genetic sequence is different.

Monsanto's strategy for defending this case has been to establish the above points. Although there are other ways to defend the case, such as asserting that Mycogen's patent is invalid, in its answer Monsanto did not assert invalidity as an affirmative defense.

Mycogen now moves the court to rule on the issue of the validity of its patent. Mycogen argues that Monsanto has waived the issue of invalidity because it did not assert it, and asks the court to rule that for the purposes of this litigation, the patent is valid. The court denies the motion. The court is convinced that Monsanto has not previously put validity at issue because it was convinced that it had other sufficiently meritorious defenses and did not want to

open up the need for discovery on validity. Monsanto has pending a motion to amend its answer to include the defense of invalidity. The court will rule on that motion when it is fully briefed, but at this point in the litigation declines to make a ruling that Monsanto has failed to establish the invalidity of Mycogen's patent.

Mycogen's Motion for Summary Judgment re: Interpretation of 35 U.S.C. § 271(g).

The basis for Mycogen's motion for summary judgment re: Interpretation of 35 U.S.C. § 271(g) is a recent Federal Circuit case. *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed.Cir. 1996) (*BTG*).

Mycogen argues that the Federal Circuit's decision in *BTG* regarding section 271(g) applies to the facts of this case as respects Monsanto's designing of genetically altered plants before the issuance of Mycogen's patent.[1] The court rejects this argument. The issues that the Federal Circuit addressed in *BTG* are not relevant to this case.

In BTG the patent holder already held a process patent at the time that alleged infringer performed the bio-technology process. Later, the allegedly infringing company attempted to market a product derived from the bio-technology process performed years earlier. The alleged infringer presented two arguments as to why it did not infringe the first company's process patent.

1. The court understands that Mycogen continues to assert that Monsanto has infringed its patent through post-issuance activities. However, those post-issuance activities are not at issue in this motion nor does not court include them its its analysis.

First, it argued that section 271(g) should not apply retroactively to processes performed before section 271(g) was enacted. The Federal Circuit rejected this argument. The court stated that there was no retroactive application of a statute, because section 271(g) created infringement for the act of selling the product produced by the patented process, not performing the process. Mycogen attempts to use this statement to argue to the court once again that it does not matter that the process is performed before the process patent issues, and that all that matters is that the product is sold during the term of the patent. However, *BTG* makes no such holding. All indications in the case are that the allegedly infringing company performed the process during the term of the process patent, unlike in Mycogen's case. The Federal Circuit thus was not deciding whether or not the process had to be in effect at the time the process was performed. All it was deciding was whether or not section 271(g) applied to processes performed before the statute was enacted.

Second, the alleged infringer in *BTG* argued that the product it was selling was not made by a patented process because the bio-technology product was not the direct product of the patented process. It argued that it fell under the exception to section 271(g) for products "materially changed by subsequent processes." The Federal Circuit held that under the facts of that case and that patent, the product was indeed closely enough related to the patented process to be considered to have been made by that process because having performed the patented process was an essential step in making the product. Mycogen attempts to use that ruling to its advantage in this case.

Appendix E

Mycogen argues that following *BTG*, Monsanto's current growing of the plants that it designed by the same process that Mycogen subsequently patented, should be considered infringement of the patented process because the growing of the plants and the designing of the plant's genes are related in the same way that the patented process and the subsequent product were related in *BTG*. In short, Mycogen is claiming that Monsanto is infringing its process patent merely by growing plants that it designed years ago because performing the process of a certain kind of gene designing is a necessary step in growing a certain kind of genetically altered plant. However, Mycogen is overlooking an extremely crucial fact. In *BTG* the original process performed by the second company was performed during the term of process patent, and thus infringed that process. Based on this, the court held that the products closely related to that first performance of the process also infringed. In Mycogen's case, however, the original process performed by Monsanto was not during the term of Mycogen's patent. There was no infringement when the process was originally performed, so there is no credible argument that the subsequent growing of plants is closely enough related to *also* infringe.

Fundamentally, both of Mycogen's arguments for the impact of *BTG* on this case are flawed because Mycogen overlooks that in *BTG* the process was performed by the alleged infringer during the term of the process patent, while in this case the process was not performed during the term of Mycogen's patent. Based on the foregoing, the court denies Mycogen's motion for summary judgment re: Interpretation of 35 U.S.C. § 271(g).

Appendix E

Monsanto's Motion for Summary Judgment on Claim Construction

Monsanto moves the court to summarily adjudicate that Mycogen's remaining theories of infringement, which it has asserted during discovery or settlement talks or during previous motion practice, are inconsistent with the language of the patent, and thus cannot form a basis for Mycogen's case.

Monsanto asks the court to make two rulings. First, Monsanto asks the court to construe the patent to exclude any type of purely abstract designing of a gene, such as writing down a genetic sequence on paper. As Monsanto points out, as a matter of patent law, purely abstract designing cannot infringe a process patent. Nor does the language of the patent support such an interpretation. In its opposition to Monsanto's motion, Mycogen does not discuss the merits of whether writing down a genetic sequence or other abstract designing constitutes infringement. The court rules that the mere abstract writing down of a genetic sequence or other purely abstract designing would not infringe Mycogen's patent.

Second, Monsanto asks the court to construe the patent to mean that Monsanto's mere current growing of plants does not infringe Mycogen's process patent when those plants were genetically designed before Mycogen's process patent issued.

The court has carefully examined the language of the process patent claim. It plainly deals with *designing genes.* The explicit steps in designing the genes are (1) analyzing a coding sequence of a gene and (2) modifying a portion of

the coding sequence. The court finds no rational basis in the language of the patent for a claim that the patent covers the subsequent method for insertion of the gene into a plant and then the natural growing process of the plant in which it makes more of its own genes. Plants do not analyze a coding sequence and plants do not modify a portion of a coding sequence. In short, under the court's construction of the patent, the process of natural growth of an already existing plant does not infringe Mycogen's patent.

Throughout its motion papers, Monsanto has suggested to the court that it should dismiss this case once it construes the patent not to include the growing of plants. However, a dismissal is not proper on a motion for claim construction. Further, as the court understands the case, post-issuance infringement is still at issue.

CONCLUSION

The court (1) denies Mycogen's motion for summary judgment of validity; (2) denies Mycogen's motion for summary judgment re: Interpretation of 35 U.S.C. § 271(g) and (3) grants Monsanto's motion for summary judgment on claim construction.

IT IS SO ORDERED.

DATED: August 15, 1996

s/ Napoleon A. Jones, Jr.
NAPOLEON A. JONES, JR.
United States District Judge

APPENDIX F — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA DENYING MYCOGEN'S MOTION FOR RECONSIDERATION DATED AND FILED APRIL 8, 1996

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Case No. 95-0653-J (LSP)

MYCOGEN PLANT SCIENCE, INCORPORATED, a Delaware corporation, and AGRIGENETICS, INCORPORATED, a Delaware corporation,

Plaintiffs,

v.

MONSANTO COMPANY, a Delaware corporation,

Defendant.

ORDER DENYING MYCOGEN'S RENEWED MOTION FOR RECONSIDERATION AND MOTION FOR RECONSIDERATION

This action is before the court on two motions for reconsideration brought by plaintiffs (Mycogen). First, Mycogen moves for reconsideration of the court's January 2, 1996 order ruling that Mycogen is estopped from relying in the doctrine of equivalents in claiming infringement of its product patent claims because of the doctrine of prosecution history estoppel. As the basis for its motion for reconsideration, Mycogen argues that Monsanto

misrepresented the correct timing of Mycogen's introduction to patent claim 53 in its briefing to the court.

The court expresses no opinion on whether in fact Monsanto's briefing contained any misleading statements. Rather, the court denies the motion for reconsideration because in arriving at its decision, set forth in the order of January 2, 1996, the court was fully aware of the timing of the introduction of patent claim 53. The court had before it the original documents representing the prosecution history and fully reviewed and considered them. Thus, the court will not consider further briefing on the effect of the timing of the introduction of claim 53. The motion for reconsideration of the order of January 2, 1996 is denied.

Second, Mycogen moves for renewed reconsideration of the court's order of September 22, 1995 regarding the meaning of 35 U.S.C. § 271(g). The court has reviewed the additional evidence submitted by Mycogen and does not find it relevant to the court's interpretation of the statute, which was based on the wording of the statute and the legislative history itself, not declarations explaining the legislative history, created for the purpose of litigation. The motion for renewed reconsideration of the order of September 22, 1995 is denied.

IT IS SO ORDERED.

DATED: April 8, 1996

s/ Napoleon A. Jones, Jr.
NAPOLEON A. JONES, JR.
United States District Judge

APPENDIX G — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA DATED DECEMBER 26, 1995 AND FILED JANUARY2, 1996

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Case No. 95-0653-J (LSP)

MYCOGEN PLANT SCIENCE, INCORPORATED, a Delaware corporation, and AGRIGENETICS, INCORPORATED, a Delaware corporation,

Plaintiffs,

v.

MONSANTO COMPANY, a Delaware corporation,

Defendant.

ORDER

This case is before the court pursuant to the further briefing ordered on the issue of the applicability of the doctrine of prosecution history estoppel to Mycogen's claim for patent infringement. Specifically, the court must decide whether Mycogen is estopped from raising the doctrine of equivalents in claiming infringement of the product claims in its patent (claims 13 and 14).

The court has thoroughly considered the briefing provided by the parties and has thoroughly reviewed the documents constituting the prosecution history that were

submitted to the court as exhibits to the requested briefing. The court holds that the doctrine of prosecution history estoppel precludes Mycogen from relying on the doctrine of equivalents to show an infringement by Monsanto of claims 13 and 14 of the '831 patent.

"Prosecution history estoppel limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of a patent." *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995). The doctrine applies both to amendments of the claim at issue and to cancellation of other claims within the context of the prosecution of the patent. *See e.g. Haynes Intern. v. Jessop Steel Co.*, 8 F.3d 1573 (Fed. Cir. 1993), *amended*, 15 F.3d 1076 (Fed. Cir. 1994) (cancellation of broader claims is a basis for prosecution history estoppel.) Ultimately, the court must make a close examination "as to, not only what was surrendered, but also the reason for such a surrender." *Southwall*, 54 F.3d at 1580.

The application of prosecution history is a question of law, and "the standard for determining whether particular subject matter was relinquished is an objective one that depends on what a competitor reasonably would conclude from the patent's prosecution history." *Mark I Marketing Corp. v. R.R. Donnelly & Sons*, 66 F.3d 285, 291 (Fed. Cir. 1995).

An examination of the prosecution history in this case reveals that Mycogen cancelled all product claims that were not limited to the exact DNA sequence contained in its gene. Among the cancelled claims was claim 2 which described

a gene 85% homologous to a native Btt gene, and claims 5 and 6 which described a gene with 75% to 90% frequency of preferred codon usage. Monsanto's gene, which Mycogen alleges infringes its product claims, falls outside of the bounds of the above cancelled claims.

The prosecution history further reveals that the above claims were rejected numerous times on the grounds of both prior art under section 103 and lack of enablement under section 112. At the time they were cancelled, claims 2, 5, and 6 had been rejected on the basis of prior art as well as lack of enablement. On the basis of this history, the court holds that a reasonable competitor would conclude that Mycogen intended to cancel all claims at least as broad as claims 2, 5 and 6 on the basis both of prior art rejections and lack of enablement in order to be able to obtain the much narrower product patent claims that issued eventually as claims 13 and 14. Thus, Mycogen is estopped from arguing that the doctrine of equivalents brings Monsanto's gene within the scope of claims 13 and 14.

In favor of the interpretation of the prosecution history briefly set forth above, the court rejects the numerous arguments asserted by Mycogen regarding the import and effect of the prosecution history. Mycogen has also argued that because it cancelled the broader claims "without prejudice" and is currently pursuing a continuation application of those claims, the court should not hold that Mycogen intended to relinquish the broader claims. The court rejects this argument. The court points out that the proper inquiry is into the scope of the claims of the '831 patent. It is irrelevant to the court's inquiry whether broader claims may eventually be approved in a future patent.

The court holds that based on the evidence of the prosecution history before it, Mycogen is estopped from relying on the doctrine of equivalents with regard to infringement of claims 13 and 14 of its patent.

IT IS SO ORDERED.

DATED: December 26, 1995

s/ Napoleon A. Jones, Jr.
NAPOLEON A. JONES, JR.
United States District Judge

APPENDIX H — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA DENYING MOTION FOR RECONSIDERATION AND APPLICATION TO CERTIFY FOR INTERLOCUTORY APPEAL DATED DECEMBER 4, 1995 AND FILED DECEMBER 5, 1995

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Case No. 95-0653-J (LSP)

MYCOGEN PLANT SCIENCE INCORPORATED, a Delaware corporation, and AGRIGENETICS, INCORPORATED, a Delaware corporation,

Plaintiff,

v.

MONSANTO COMPANY, a Delaware corporation,

Defendant.

ORDER DENYING MOTION FOR RECONSIDERATION; DENYING APPLICATION TO CERTIFY FOR INTERLOCUTORY APPEAL

Mycogen has moved for reconsideration of the portion of the court's order of September 22, 1995 rejecting Mycogen's novel interpretation of 35 U.S.C. § 271(g) as well as of the portion of the court's order holding that Monsanto does not infringe on Mycogen's product patent claim by maintaining plantlets covered by Mycogen's patent.

Appendix H

Interpretation of 35 U.S.C. § 271(g)

As the court explained in its order of September 22, 1995, section 271(g) states:

> Whoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, sale or use of the product occurs during the term of such process patent.

In opposition to Monsanto's motion for summary judgment on the process patent claim, Mycogen had focused on the final phrase of the statutory language and had argued that the infringing product need not have been manufactured during the term of the process patent to create infringement. Rather, Mycogen argued that all that was required was that the importation, sale or use occur during the term of the process patent. With its interpretation, Mycogen sought to impose liability on Monsanto for whatever gene development it may have performed before the Mycogen process patent issued. The court's order clearly rejected this interpretation based on the clear language of the statute, the legislative history, and the extreme, apparently unintended result that Mycogen's reading would have on altering the term of United States process patents.

Mycogen now moves for reconsideration and has approached this motion with a novel procedural argument. Mycogen argues that the court should reexamine its decision de novo because Mycogen was deprived of an opportunity to present its interpretation of section 271(g). Mycogen argues that

its opposition papers were not a sufficient forum because Monsanto's theory of the meaning of section 271(g) was not presented until the reply brief, and the court refused the application to file a surreply and also indicated at oral argument that it did not require argument on the issue of section 271(g). The court rejects Mycogen's procedural argument and has not reexamined its ruling de novo. Mycogen had a sufficient opportunity to set forth its best case regarding its interpretation of section 271(g) in its opposition papers.

Having considered Mycogen's motion for reconsideration under the standards set forth in Local Rule 7.1(i) and Federal Rule of Civil Procedure 60(b), the court denies the motion. Although its moving papers are lengthy and it has submitted voluminous additional evidence in the form of declarations and excerpts from legislative history, Mycogen has presented no evidence or argument that would cause the court to reconsider its previous holding. As the court's order explained, the most relevant evidence of the meaning of section 271(g) is the language of the statute itself and the legislative history. These two clearly point to the result that the court arrived at in the order of September 22, 1995. Thus, the court denies the motion for reconsideration of its interpretation of section 271(g).

Reconsideration of Ruling on Plantlets

Mycogen also seeks reconsideration of the court's ruling that keeping alive the identical plantlets by Monsanto (plantlets which are admitted to fall under Mycogen's product patent) do not constitute an infringing use of the product because they are merely being maintained.

Mycogen presents no compelling reason why the court should reconsider the ruling regarding the maintenance of the plantlets. Rather, it simply disagrees with the court's resolution. Thus, the court denies the motion to reconsider that ruling as well.

Interlocutory Appeal

The final issue raised by Mycogen is certification for interlocutory appeal. Mycogen requests that pursuant to 28 U.S.C. § 1292(b) the court certify for review by the Federal Circuit the issue of the proper interpretation of section 271(g). Monsanto also agrees that the question should be certified for interlocutory appeal. However, Monsanto argues that pending the resolution of the prosecution history estoppel issue, which this court has under submission, there may be a final judgment in this case, and that Mycogen can then take a normal post-judgment appeal. Monsanto also states that if the court does not enter final judgment in this case in the near future, it agrees that the section 271(g) should be certified for interlocutory appeal because the issue of pre-issuance infringement is a central issue.

The court points out that the pending ruling on the issue of prosecution history estoppel could not resolve all of the issues in this case. The prosecution history estoppel decision will resolve only whether the product patent claims are barred. According to the court's order of September 22, 1995, there will still remain discovery to be conducted on the pre-issuance process claims. Further, there are several state law claims still pending. Pursuant to 28 U.S.C. § 1292(b) an interlocutory appeal may be taken "[w]hen a district judge, in making in a civil action an order not otherwise appealable under this

section, shall be of the opinion that such an order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation."

The court agrees that an immediate appeal from the order may materially advance the ultimate termination of the litigation. However, the court also finds that there is not a substantial ground for difference of opinion. Rather, the court is convinced that there is no credible argument to be made that section 271(g) applies products manufactured outside the term of the process patent. Thus, the court denies the motion for certification for interlocutory appeal.

Conclusion

The court denies the motion for reconsideration and the application to certify for interlocutory appeal.

IT IS SO ORDERED.

DATED: December 4, 1995

s/ Napoleon A. Jones, Jr.
NAPOLEON A. JONES, JR.
United States District Judge

APPENDIX I — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA RULING IN PART ON DEFENDANT'S SUMMARY JUDGMENT AND ORDERING FURTHER BRIEFING ON ISSUE OF PROSECUTION HISTORY ESTOPPEL DATED AND FILED SEPTEMBER 22, 1995

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Case No. 95-0653-J (LSP)

MYCOGEN PLANT SCIENCE, INCORPORATED, a Delaware corporation, and AGRIGENETICS, INCORPORATED, a Delaware corporation,

Plaintiffs,

v.

MONSANTO COMPANY, a Delaware corporation,

Defendant.

ORDER RULING IN PART ON DEFENDANT'S SUMMARY JUDGMENT; ORDERING FURTHER BRIEFING ON ISSUE OF PROSECUTION HISTORY ESTOPPEL

This action is before the court on defendant Monsanto's motion for summary judgment on the patent infringement claim involving a patent issued in January 1995 to plaintiff Mycogen.

I. THE PATENT

The patent at issue in this suit deals with a method of inserting a gene resembling a naturally occurring bacterial toxin into

agricultural plants to cause the plants to produce a protein that is harmful to insects. The genes are designed to contain the same sequence of amino acids found in the DNA of the toxic bacteria, but to use different nucleotides (the building blocks of DNA) to produce the amino acid sequences. There are several different ways to encode an amino acid, using different nucleotides. The nucleotides used in Mycogen's process are naturally dominant in the plants rather than in the bacteria, though the resultant amino acid sequence is the same as in the bacteria. The genes are then inserted into plant tissue; the plants are cultivated and reproduced to produce commercially viable insect resistant plants. Because there are many different ways to arrange to the nucleotides to produce an amino acid sequence identical to the amino acid sequence in the toxic bacteria, there is more than one way to achieve the desired result of a plant that produces the bacterial toxin.

Mycogen's patent has two types of claims: process claims and product claims. The process claims cover the method for creating the genes. The product claims cover the genes themselves and are illustrated by a diagram of the exact nucleotide sequence used by Mycogen.

Defendant Monsanto is also involved in developing insect resistant plants through gene design and has been developing such plants for several years. In May 1995, Monsanto received permission from the Environmental Protection Agency to commercialize an insect resistant potato plant, the New Leaf potato, which contains toxin based on genes from the same bacteria as the bacteria covered by the Mycogen patent. However, the nucleotide sequence is not identical. Monsanto has used different nucleotides to achieve substantially the same

amino acid sequence as in the naturally occurring bacteria. Monsanto maintains that it has not conducted any development using the method covered by Mycogen's patent since the patent was issued in January. For the purposes of this motion, Monsanto assumes for the sake of argument that the genetic designing it performed before January was the same as that covered by Mycogen's process claims.

II. LEGAL ANALYSIS

Mycogen's suit against Monsanto alleges that Monsanto has infringed the patent by violating both the process and product claims. Mycogen has also asserted several state law claims which are not at issue in this motion. Monsanto moves for summary adjudication of non-infringement on the patent claim. Mycogen counters, in part, that more discovery is needed before the court may decide the summary judgment. For the reasons set forth below, the court holds that many of the issues presented by this motion may be summarily adjudicated without further discovery. However, the issue of Monsanto's activities occurring after the issuance of the patent cannot be dealt with as a matter of law, and thus are not yet ripe for summary judgment. Mycogen will be permitted to conduct further discovery on Monsanto's post-issuance activities.

A. *PROCESS CLAIMS*

The central dispute presented by Monsanto's motion for summary judgment on the process claims is whether the patent creates liability for Monsanto's *pre-issuance* gene designing.

Mycogen urges the court to adopt a novel interpretation of the patent laws. It argues that a party infringes a process patent

even if the process was performed *before* the patent issued, as long as the party commercializes the product that is the result of the process *after* the patent issues. Thus, Mycogen argues that the sale of the New Leaf potato plant, if designed by the process subsequently patented by Mycogen, would constitute patent infringement. The court rejects this argument.

Normally a United States process patent creates exclusivity from the time that the patent issues and gives the process patent holder the right to exclude all others from practicing that process within the United States. "A method or process claim is directly infringed . . . when the process is performed." *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993). As the court understands the legislative history, this scheme created problems when a process was performed outside the United States and the resulting product was sold in the United States. If a patent holder held only a process claim but not a product claim (as is necessarily the case in many bio-tech patents), it could not stop the goods from being manufactured abroad by the patented process and being sold in the United States in competition with the goods made under license. Thus, in 1988 Congress enacted 35 U.S.C. § 271(g) which made it an act of infringement to import or sell goods made by a patented process.

> Whoever without authority imports into the United States or sell or used within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent.

35 U.S.C § 271(g).

Mycogen argues that section 271(g) should be interpreted to encompass products manufactured before the issuance of the patent as long as the product is sold, used, or imported during the patent term. Mycogen argues that its position draws support from two sources.

First, Mycogen looks to the language of the statute itself. Mycogen points out that the statute specifically provides that the sale, use or importation must occur during the term of the patent, but does not so specify for the employment of the process itself. Monsanto counters that the statute does specify that the process must be employed during the term of the patent because it refers to "a product which is made by a process *patented* in the United States." The court holds that though it understands the reasons for Mycogen's interpretation, based on the language of the statute itself, the clearly preferable reading is that of Monsanto: since the statute refers to a "patented" process it implies that the process patent has to have been issued at the time of the employment of the process for the statute to apply.

Second, Mycogen points to legislative history. Mycogen focuses (1) on the different versions of the legislation that was eventually passed as § 271(g), and (2) on statements made by persons who testified before Congress. The court has closely reviewed both of the above elements of the legislative history and finds that neither is convincing.

The different versions of the proposed bills simply do not support the theory that Congress was ever considering the interpretation urged by Mycogen. Rather, at most they support the inference that Congress was at one time considering imposing no limit on the time period in which the product had to be sold, used or imported.

Appendix I

The testimony before Congress isolated by Mycogen is also not probative. Most of the comments were made three years before the law was eventually enacted, and the comments are not from Congress members. Rather, they are from members of the public testifying as to their understanding of the possible impacts of the proposed bills. The Supreme Court has held that testimony of members of the public before Congress need not be accorded significance in interpreting a statute. *See Kelly v. Robinson*, 479 U.S. 36, 51 n.13 (1986).

The more probative pieces of legislative history are the committee reports prepared by the House and Senate. The court has closely reviewed the committee reports and finds that they contain no support for Mycogen's interpretation. Further, all of the relevant statements in the committee reports tend to support the interpretation that the statute only applies when the process is employed during the term of the process patent. For example, the Senate Report states that the bill "would protect against the entry into the U.S. marketplace of goods *made abroad without authorization from the inventor who has a process patent* in this country." Senate Report 100-83, Process Patent Amendments Act of 1987, June 23, 1987, at 30 (emphasis added). Another phrase refers to a determination of "whether the goods are *being manufactured* by a process patented in the United States." *Id.* at 40 (emphasis added).

Mycogen has submitted a declaration from an expert who was involved in the legislative process. The declaration expresses support for Mycogen's position. The court rejects this declaration as irrelevant to the question of statutory interpretation which is a task for the court to carry out by looking at the language of the statute and the legislative history, rather than by surveying expert opinion.

In sum, the court finds no support for Mycogen's position either in the text of the statute or in the legislative history. Thus, the court summarily adjudicates that Monsanto cannot have infringed Mycogen's process patents based on any process it performed before the patent issued.

B. *PRODUCT CLAIMS*

1. *Doctrine of Equivalents*

Two of the claims in the Mycogen patent are for the DNA sequence itself. The claims read:

> 13. A synthetic gene comprising the DNA sequence presented in FIG. 1, spanning nucleotides 1 through 1793.
>
> 14. A synthetic gene comprising the DNA sequence presented in FIG. 1, spanning nucleotides 1 through 1833.

The term "comprising" is a term of art meaning that additional unrecited elements are not excluded as long as the recited elements are present. *See Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271 (Fed. Cir. 1986). Thus, another gene could literally infringe the patent even if it added other elements as long as it included the nucleotides in Fig. 1.

The gene for the Monsanto New Leaf potato does not include all of the nucleotides in Fig. 1. There are differences, primarily because Monsanto has used other nucleotides to create the same amino acids. There is approximately a 19% difference between the two genes. Thus, there is no literal infringement.

However, Mycogen argues that under the doctrine of equivalents there is a genuine issue of fact as to whether the gene used in the New Leaf potato infringes Mycogen's patented gene. Under the doctrine of equivalents a product may infringe if the finder of fact determines that the differences between the product and the patent are "insubstantial" and "merely colorable." *Hilton Davis v. Warner-Jenkins*, 35 U.S.P.Q.2d 1641 (Fed. Cir. 1995) (en banc). Thus, there need not be literal infringement of the patented gene set forth in Figure 1 of the patent for Mycogen to show infringement — it need only show that the two genes have insubstantial differences.

It is Mycogen's position that there are insubstantial differences between its patent claim and Monsanto's gene used in the New Leaf potato, and a finder of fact should be asked to determine whether the New Leaf gene infringes. At this point in the litigation, before substantial discovery and collection of expert opinion, the court is unable to adjudicate whether there is a genuine issue for the finder of fact regarding the substantial identity of the two genes. Thus, at this point in the litigation, the court will not summarily adjudicate whether there is a genuine issue of fact regarding application of the doctrine of equivalents.

2. *Prosecution History Estoppel*

Monsanto argues that Mycogen is estopped from raising the doctrine of equivalents because of prosecution history estoppel. "Prosecution history estoppel limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of a patent." *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995). Whether prosecution history estoppel applies is a question of law. *See e.g. Southwall*, 54 F.3d at 1579.

"When a court applies the doctrine of prosecution history estoppel to limit the scope of equivalents, a close examination must be made as to, not only what was surrendered, but also the reason for such a surrender." *Id.* at 1580 (internal quotation omitted). For example, prosecution history estoppel is most commonly applied to surrenders made because of prior art objections, *Hi-Life Products v. American National Water-Mattress*, 842 F.2d 323, 325 (Fed. Cir. 1988), but not necessarily to claims dropped because of indefiniteness. *Mannesmann Demag Corp. v. Engineered Metal Products*, 793 F.2d 1279, 1285 (Fed. Cir. 1986) ("Prosecution history estoppel is not necessarily created by an amendment designed only to remove a § 112 indefiniteness rejection.").

During the prosecution of the product claims, Mycogen originally included claims that were broader than those which were eventually included in the patent. Monsanto argues that this prosecution history estops Mycogen from asserting that Monsanto's gene, which has an approximate 19% difference from Mycogen's gene, is infringing under the doctrine of equivalents.

The parties have not extensively briefed the issue of prosecution history estoppel. Before issuing a ruling on whether prosecution history estoppel bars Mycogen from relying on the doctrine of equivalents, the court requests the parties to extensively brief the issue, concentrating on a description of the prosecution history itself and the significance of that history to the creation of estoppel.

The briefs shall be submitted as follows. Monsanto shall submit a brief, not to exceed 20 pages, by October 6, 1995. Mycogen shall submit an opposition brief by October 13, 1995,

not to exceed 20 pages. Monsanto shall submit a reply by October 20, 1995, not to exceed 15 pages. The court will then rule. The briefing shall include detailed citations to the documents constituting the prosecution history, and the parties shall resubmit as exhibits all documents referred to in their briefing.

3. *Maintenance of Plants Containing Patented Genes*

Under the heading of the product claims, there is another distinct issue that the court must address. Monsanto has admitted that in the past, before the patent issued, it made the exact gene covered by the Mycogen patent. This gene was inserted into plants, and Monsanto still has cuttings of these plants that it is maintaining in its laboratories. These plants contain genes that are identical to the products covered by Mycogen's product claims. All of the evidence before the court indicates that the maintenance consists only of making sure the cuttings continue to survive.

Monsanto would infringe the patent if it were to "make, use or sell" the patented product — i.e., the genes. Mycogen argues that by maintaining the cuttings, Monsanto is infringing Mycogen's product claims. The court rejects this argument as a matter of law. The court holds that the mere maintenance of plants containing the genes does not constitute a use or contemplated use of the patent's inventive features. The court emphasizes that its ruling is without prejudice to Mycogen presenting further evidence that Monsanto has done more than merely maintain the cuttings since the patent issued.

Appendix I

III. CONCLUSION

The court summarily adjudicates that section 271(g) does not apply to products made before the process patent issued. Thus, Monsanto could not have infringed Mycogen's patent based on its activities prior to the issuance of the patent. However, the court will allow further discovery on post-issuance infringement before entertaining a summary judgment motion on that aspect of Mycogen's patent infringement claim.

With reference to the product claims, the court requires further briefing before ruling whether prosecution history estoppel bars Mycogen's reliance on the doctrine of equivalents. The parties shall provide further briefing according to the schedule set forth above.

IT IS SO ORDERED.

DATED: September 22, 1995

s/ Napoleon A. Jones, Jr.
NAPOLEON A. JONES, JR.
United States District Judge

FILED
JAN 15 2002

No. 01-740

In the Supreme Court of the United States

MYCOGEN PLANT SCIENCE, INC.
AND AGRIGENETICS, INC.,
Petitioners,

v.

MONSANTO COMPANY,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1) Whether the doctrine of prosecution history estoppel forecloses a patentee (Mycogen) from relying on the doctrine of equivalents to prove infringement of product claims that are limited to the exact synthetic gene disclosed in the '831 patent where Mycogen intentionally surrendered all broader patent claims to overcome prior art rejections during prosecution, including canceling claims that were too narrow to encompass Monsanto's accused gene?

2) Whether the Court of Appeals correctly held that there can be no infringement liability under 35 U.S.C. § 271(g) with respect to use or sale of products during the term of the asserted process patent, where such products could not have been "made by a process patented in the United States" at the time that the accused process was performed because the asserted United States process patent had not issued yet?

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, respondent Monsanto Company ("Monsanto") states that Pharmacia Corporation is a publicly-traded corporation that currently owns more than 10% of Monsanto's stock. Respondent further states that all parties appear in the caption of the case on the cover page.

TABLE OF CONTENTS

QUESTIONS PRESENTED i

RULE 29.6 STATEMENT ii

OPINIONS BELOW 2

JURISDICTION 3

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED 3

STATEMENT OF THE CASE 4

A. Nature and Stage of the Proceedings 4

1. The District Court's Rulings 5

2. The Federal Circuit's Rulings 7

B. The Prosecution History Shows That Mycogen Canceled Product Claims That Were Too Narrow To Encompass Monsanto's Accused Gene 10

REASONS FOR DENYING THE PETITION 13

A. Mycogen Cannot Avoid Prosecution History Estoppel Simply Because Its Claims Limited To The Figure 1 Gene Were Not Narrowed 16

B. The Federal Circuit's Interpretation Of 35 U.S.C. § 271(g) Was Completely Correct 23

CONCLUSION 28

TABLE OF AUTHORITIES

Page(s)

CASES

Bio-Technology General Corp. v. Genentech, Inc.,
80 F.3d 1553 (Fed. Cir. 1996) 8, 25, 26

Exhibit Supply Co. v. Ace Patents Corp.,
315 U.S. 126 (1942) 13, 18, 21, 22

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000), *cert. granted*, No. 00-1543 (June 18, 2001) ..... *passim*

Genentech, Inc. v. Wellcome Found. Ltd.,
29 F.3d 1555 (Fed. Cir. 1994) 19

Gwaltney v. Chesapeake Bay Foundation,
484 U.S. 49 (1987) 24

Hoganas AB v. Dresser Indus., Inc.,
9 F.3d 948(Fed. Cir. 1993) 19

In re Amtorg Trading Corp.,
75 F.2d 826 (C.C.P.A. 1935) 26

Keystone Driller Co. v. Northwest Engineering Corp.,
294 U.S. 42 (1935) 18

Landreth Timber Co. v. Landreth,
471 U.S. 681 (1985) 23

Lemelson v. General Mills, Inc.,
968 F.2d 1202 (Fed. Cir. 1992) 19

Mark I Marketing Corp. v. R.R. Donnelly & Sons,
66 F.3d 285 (Fed. Cir. 1995) 16, 17

Mycogen Plant Science, Inc. v. Monsanto Co.,
61 F. Supp. 2d. 199 (D. Del. 1999), *aff'd*, 243
F.3d 1316 (Fed. Cir. 2001) 6, 7

RJR Nabisco, Inc. v. United States,
955 F.2d 1457 (11th Cir. 1992) 28

United States v. Mortons,
467 U.S. 822 (1984) 24

Wang Labs., Inc. v. Toshiba Corp.,
993 F.2d 858 (Fed. Cir. 1993) 19, 21

Warner-Jenkinson Co. v. Hilton Davis Chemical Co.,
520 U.S. 17 (1997) 18, 22

Zenith Labs., Inc. v. Bristol-Meyers Squibb Co.,
19 F.3d 1418 (Fed. Cir. 1994) 21

STATUTES

28 U.S.C. § 1254(1) 3

28 U.S.C. § 1292(b) 5

28 U.S.C. § 1295(a)(1) 3

28 U.S.C.§ 1338(a) 3

35 U.S.C. § 102(g) 6, 7

35 U.S.C. § 103 ..... 6, 7

35 U.S.C. § 112 ..... 6, 7

35 U.S.C. § 271(g).....*passim*

LEGISLATIVE REPORTS

H.R. Conf. Rep. No. 576, 100th Cong., 2d Sess. 1086 (1988) 28

H.R. Rep. No. 807, 96th Cong., 2d Sess. 19 (1986).....26

S. Rep. No. 83, 100th Cong., 1st Sess., Sec. III (1987) ...26, 27

S. Rep. No. 388, 100th Cong., 2d Sess. 33 (1988).....26

S. Rep. No. 663, 98th Cong., 2d Sess., Sec. IV (1984).....27

In the Supreme Court of the United States

No. 01-740

MYCOGEN PLANT SCIENCE, INC. AND AGRIGENETICS, INC.,
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v.

MONSANTO COMPANY,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

Respondent Monsanto Company respectfully urges the Court to deny the petition for a writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit. While the doctrine of equivalents issue in this case was resolved by the Federal Circuit by applying its decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000), *cert. granted*, No. 00-1543 (June 18, 2001), the prosecution history estoppel and the noninfringement outcome are correct under "pre-*Festo*" law and thus are not dependent upon the Federal Circuit's "complete bar" rule announced in *Festo*.

Because Mycogen canceled claims that had been rejected over prior art but were themselves too narrow to cover Monsanto's accused gene, this petition can and should be denied no matter how this Court resolves the *Festo* case because Mycogen clearly surrendered the coverage that

would have been needed for the '831 patent to reach the accused products. Moreover, the Federal Circuit's decision construing 35 U.S.C. § 271(g) is clearly correct, and does not warrant review by this Court.

OPINIONS BELOW

The Federal Circuit's decision resolving the issues for which review is being sought is reported at 252 F.3d 1306 (Fed. Cir. 2001), and is reproduced at Petitioner's Appendix (Pet. App. 13a-38a). The relevant portions of that opinion addressing the two issues raised by the petition are found at Pet. App. 36a-38a (prosecution history estoppel), and at Pet. App. 32a-35a (interpretation of 35 U.S.C. § 271(g)). The Federal Circuit's supplemental opinion denying Mycogen's petition for rehearing on the prosecution history estoppel issue is reported at 261 F.3d 1345 (Fed. Cir. 2001), and is reproduced at Pet. App. 1a-12a.

The district court's decisions are not published. The district court's order of September 22, 1995 held that 35 U.S.C. § 271(g) did not apply to products made before the process patent in question issued, and is reproduced at Pet. App. 109a-119a. The district court's order of December 4, 1995 denied Mycogen's motion for reconsideration and interlocutory appeal of the earlier section 271(g) ruling, and is reproduced at Pet. App. 104a-108a. The district court's order of December 26, 1995 held that Mycogen was estopped from asserting infringement of its product claims 13 and 14 under the doctrine of equivalents, and is reproduced at Pet. App. 100a-103a.

The district court's order of April 8, 1996 denied Mycogen's motion for reconsideration of the prosecution history estoppel ruling and Mycogen's renewed motion for reconsideration of the § 271(g) ruling, and is reproduced at Pet. App. 98a-99a. The district court's order of August 15,

1996 included a denial of Mycogen's third motion for reconsideration of the § 271(g) ruling (that was styled as being a motion for summary judgment on the interpretation of 35 U.S.C. § 271(g)), and is reproduced at Pet. App. 91a-97a. The district court's order of November 10, 1999 that disposed of the remaining issues in the case does not relate to any issue raised by the petition, but is reproduced at Pet. App. 40a-90a.

JURISDICTION

The district court had jurisdiction under 28 U.S.C.§ 1338(a). The jurisdiction of the Court of Appeals was based on 28 U.S.C. § 1295(a)(1). The decision of the Court of Appeals denying rehearing of its May 30, 2001 decision was rendered on August 14, 2001. This Court has jurisdiction under 28 U.S.C. § 1254(1). The petition for certiorari was docketed on November 28, 2001. The time for filing this opposition was extended until January 15, 2002.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

With respect to the prosecution history estoppel and the doctrine of equivalents issue, there are no constitutional or statutory provisions to be interpreted in this case. As explained herein, the decision at issue involves a case-specific application of the doctrine of prosecution history estoppel, which is itself a limitation on the judicially-created doctrine of equivalents as may be applied in certain patent infringement cases.

The other issue presented by the petition concerns the proper construction of 35 U.S.C. 271(g), which provides:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States

a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after –

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential compenent of another product.

STATEMENT OF THE CASE

A. Nature and Stage of the Proceedings

On May 23, 1995, Mycogen filed this case in the United States District Court for the Southern District of California asserting that Monsanto infringed Mycogen's U.S. Patent No. 5,380,831 ("the '831 patent") based upon the genes in certain of Monsanto's insect-resistant crops. Pet. App. 41a. The '831 patent contained 14 claims. Notably, claims 1-12 were "process" claims while claims 13-14 were "product" claims.

Claims 1-12 of the '831 patent were directed to a process of analyzing and modifying the native *Bacillus thurigiensis* ("*Bt*") gene to more closely resemble a plant gene with the goal of increasing its expression in plants. Figure 1 of the patent discloses the '831 patent's single example of a modified *Bt* gene, which includes hundreds of

changes to the nucleotide sequence present in the native *Bt* gene. Claims 13 and 14, the two product claims, are directed to the specific gene sequence illustrated in Figure 1 of the patent. Pet. App. 110a.

1. The District Court's Rulings

For purposes of determining whether Monsanto's accused activities could result in infringement liability under 35 U.S.C. § 271(g), the two relevant facts were undisputed. First, the parties agreed that the Monsanto products for which infringement damages were being sought by Mycogen were developed by Monsanto using a process performed before the '831 patent issued. Second, for purposes of the summary motion, Monsanto agreed that the process that it used before the '831 patent issued would be presumed to fall within the scope of one or more of Mycogen's later-issued process claims 1-12. Hence, Monsanto's motion for noninfringement under § 271(g) presented a pure issue of statutory construction to be resolved as a matter of law.

On September 22, 1995, the district court granted summary judgment for Monsanto that it could not infringe Mycogen's process claims (claims 1-12) under 35 U.S.C. § 271(g) with respect to any Monsanto genes had been designed and made before the '831 patent issued. Pet. App. 111a-115a. As noted, Mycogen immediately moved for reconsideration and to have the ruling certified for interlocutory appeal under 28 U.S.C. § 1292(b), but those motions were denied. Pet. App. 104a-108a (district court found no substantial ground for difference of opinion because "there is no credible argument to be made that section 271(g) applies to products manufactured outside the term of the process patent").

On December 26, 1995, the district court held that prosecution history estoppel prevented Monsanto's genes from infringing the two '831 product claims (claims 13-14) under the doctrine of equivalents because Mycogen had cancelled all product claims that were not limited to the exact DNA sequence shown in Figure 1 and because some of the cancelled claims were too narrow to cover Monsanto's accused gene.[1] Pet. App. 100a-103a. While those rulings disposed of most of Mycogen's infringement case, a final judgment could not be entered because Mycogen alleged that some infringement of process claims 1-12 had occurred after the '831 patent had issued.

On March 30, 1998, Monsanto filed two motions for summary judgment that claims 1-12 were invalid: one based upon 35 U.S.C. §§ 102(g) and 103 in light of Monsanto's prior invention, and one based upon 35 U.S.C. § 112 for lack of enablement. A1120-50; A1156-85. The former relied in part upon the collateral estoppel effect of the judgment in *Mycogen Plant Science, Inc. v. Monsanto Co.*, 61 F. Supp. 2d. 199 (D. Del. 1999), *aff'd*, 243 F.3d 1316 (Fed. Cir. 2001). In that case, the Delaware court upheld a jury verdict that two Monsanto scientists were prior inventors of the subject matter claimed in two related Mycogen patents based on the same inventive acts and specification as the '831 patent at issue here. *See* 61 F. Supp. 2d at 209-10; 235-42.

Because the Delaware trial on Mycogen's related patents was tried first, the California court stayed further proceedings in this case until the Delaware court resolved its post-trial JMOL and new trial motions. The Delaware court upheld that jury's invalidity verdict under § 102(g) and

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[1] Mycogen necessarily conceded the absence of literal infringement because Monsanto's gene differed more than 20% from the nucleotide sequence shown in Figure 1. Pet 11; Pet. App. 36a.

separately granted JMOL for Monsanto that the '600 and '862 patents were invalid for lack of enablement. 61 F. Supp. 2d at 257-60.

On November 10, 1999, the California district court lifted its stay and granted summary judgment that the two independent process claims in the '831 patent (claims 1 and 11) were invalid under 35 U.S.C. § 102(g) and that the dependent process claims were invalid under 35 U.S.C. § 103, based on Monsanto's accused genes being an earlier invention of the claimed subject matter by Monsanto. Pet. App. 50a-90a. The district court did not decide Monsanto's separate § 112 invalidity motion, holding that it was moot. Pet. App. 90a. Mycogen then appealed the final judgment to the Federal Circuit.

2. The Federal Circuit's Rulings

On May 30, 2001, the Federal Circuit affirmed that the Delaware judgment on the related Mycogen patents meant that Monsanto was the first to reduce the invention claimed in the '831 process claims to practice, but held that Monsanto had not established an absence of genuine issues of material fact over whether Mycogen had been the first to conceive and then diligently reduce the invention to practice. Pet. App. 17a-30a. Thus, the Federal Circuit reversed the summary judgment of invalidity under 35 U.S.C. § 102(g) and § 103, and remanded those issues to the district court.[2]

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[2] Upon remand, the district court ordered supplemental briefing on Monsanto's summary judgment motion that claims 1-12 were invalid under § 112 that was previously denied as moot. That briefing was completed on December 10, 2001. If that motion is granted, further proceedings with respect to the remanded invalidity issue of claims 1-12 under § 102(g) and with respect to the § 271(g) issue raised by Mycogen's petition would be unnecessary to the resolution of this case.

The Federal Circuit affirmed the district court's statutory construction ruling that Monsanto could not be liable under § 271(g), for infringement of claims 1-12 based on having performed its accused process before the '831 patent issued.

> We think Monsanto has the better of the argument based on the language of § 271(g). In the phrase "a product which is made by a process patented in the United States" the verbs "made" and "patented" are part of a parallel construction, which suggests that for infringement to be found the process must be patented at the time the product is made.

Pet. App. 34a. The Federal Circuit agreed that its decision in *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996), did not address that question. Pet. App. 33a. Moreover, the Court of Appeals recognized that the purpose of § 271(g) had been to grant patent holders the same protection against foreign infringers that they had against domestic infringers, and there was no remedy accorded on a process patent against domestic entities that practice a process before a patent on that process issues. Pet. App. 34a-35a. Hence, the Federal Circuit affirmed that § 271(g) requires that "the patent be issued and in force at the time that the process is practiced and the product is made." Pet. App. 35a.

With respect to the district court's ruling that prosecution history estoppel foreclosed any infringement of claims 13 and 14 under the doctrine of equivalents, the Federal Circuit also affirmed. Pet. App. 36a-38a. The Court of Appeals recognized that the two product claims had not been amended. Pet. App. 37a. However, the Court discerned

no legally-significant difference between canceling a claim having a broad limitation and replacing it with a claim having a narrower limitation, and amending a claim to narrow a limitation. Pet. App. 37a-38a. Noting that this concept was not a new development under the doctrine of prosecution history estoppel, Pet. App. 38a, the Federal Circuit then applied its *Festo* decision to hold that Mycogen was entitled to no range of equivalents. *Id.*

Mycogen petitioned for rehearing on the prosecution history estoppel issue only, asserting that the Federal Circuit had apparently not understood the prosecution history of the '831 patent. Making arguments similar to those in its present petition, Mycogen asserted that its two product claims based on the Figure 1 sequence had been in its original application and were only amended to depend from a succession of broader claims (that were never allowed and eventually canceled). According to Mycogen, the two allowed claims had never themselves been narrowed, so the rationale of the Federal Circuit's *Festo* decision did not apply to foreclose the doctrine of equivalents.

Somewhat unusually, the Federal Circuit panel denied rehearing in a supplemental opinion which demonstrated that the panel fully understood Mycogen's prosecution history, despite having not recited it in detail in the original opinion. Pet. App. 1a-12a. As summarized therein:

> [T]he examiner in this case made clear that in light of the unpredictability of expression of synthetic genes, demonstration of enablement was required for allowance. The examiner also was clear that when only one synthetic gene was shown to be enabled, no broader claim scope was allowable. Faced with these rejections, Mycogen acquiesced in the

> examiner's proposal to cancel all claims except those specifically reciting the Figure 1 sequence. Thus, the prosecution history reveals that what the examiner ultimately proposed, and Mycogen accepted, was claim language limited to sequences taken from the preferred embodiment set forth in Figure 1. Under these circumstances, it is appropriate to limit Mycogen to the literal scope of the claims to which it agreed.

Pet. App. 11a-12a.

B. The Prosecution History Shows That Mycogen Canceled Product Claims That Were Too Narrow To Encompass Monsanto's Accused Gene

Mycogen concedes that the two product claims in the '831 patent literally cover only the specific nucleotide sequence pictured in Figure 1 of the patent. Pet. 7. Specifically, claim 13 is to a gene comprising nucleotides 1 through 1793 of the sequence shown in Figure 1, while claim 14 is to a gene comprising nucleotides 1 through 1833 of that sequence. *Id.* However, purportedly because the prosecution history of the '831 patent is too "complex" to be summarized any more than "briefly" in the petition, Mycogen's petition omits several key facts that are determinative of the prosecution history estoppel issue.

Mycogen's attack on the Federal Circuit's application of prosecution history estoppel under *Festo* is premised solely upon claims 13 and 14 not being the subject of a "narrowing" amendment during prosecution. *See, e.g.*, Petition, at 22-23. What Mycogen's petition conveniently fails to mention is that those two product claims could hardly have been the subject of a narrowing amendment because

they were already the narrowest possible product claims that could be in the application – limited specifically to two different DNA lengths of the "exact" nucleotide sequence shown in Figure 1.[3]

Throughout the prosecution of the '831 patent, the PTO refused to issue product claims broader than the precise DNA sequence of the Figure 1 gene. Pet. App. 9a, 11-12a. In all, Mycogen sought over 40 such claims. As the district court and the Federal Circuit explained, the PTO rejected every one as obvious over or as anticipated by prior art and as not enabled by Mycogen's specification. Pet. App. 101a-102a; Pet. App. 3a-9a. Mycogen eventually canceled all such broader product claims to obtain the '831 patent. Pet. App. 11a-12a.

It cannot be disputed that some of the claims sought and ultimately canceled by Mycogen to overcome prior art rejections were too narrow to encompass Monsanto's accused gene.[4] For example, Mycogen's prosecution claim 2 was directed to a synthetic gene having a DNA sequence "at least about 85% homologous to a native insecticidal protein gene of *Btt.*" Pet. App. 101a-102a. In contrast, Monsanto's

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[3] The gene in Figure 1 of the '831 patent is a synthetic *Bt* gene that differs from the corresponding native *Bt* gene in about 11% of the nucleotides. *See* Kemp/Sutton Declaration (Table 1). Moreover, the '831 patent states that the synthetic gene is preferably "at least approximately 85% homologous to an insecticidal protein gene of *Bt*," *i.e.*, that the synthetic gene be no more than 15% different than the native gene.

[4] Monsanto's *Bt* gene accused under claims 13 and 14 is the gene in Monsanto's NewLeaf® potato, which has changes to about 22% of the nucleotides of the native *Bt* gene. Kemp/Sutton Declaration (Table 1). There is also a difference of about 21% between Monsanto's accused gene and the Figure 1 gene. *Id.* Thus, Monsanto's accused gene is outside the preferred 15% range in the '831 patent and is more different from the Figure 1 gene than the Figure 1 gene is from the native *Bt* gene.

accused gene has less than 78% homology with the native *Bt* gene and thus was literally outside the scope of canceled prosecution claim 2. *See supra* note 4.

Similarly, Mycogen's canceled prosecution claims 5-6 required that the overall frequency of preferred codon usage be within about 75% or 90% of the frequency of codon usage preferred in plants, as shown in Table 1 of the '831 patent specification. Pet. App. 37a. Those canceled claims would also have been too narrow to cover Monsanto. Monsanto's accused gene has a frequency of preferred codon usage of only 51%, which is much lower than the minimum 75% in prosecution claims 5-6. *See* Fischhoff Declaration (¶ 17).

Mycogen then rewrote prosecution claim 1 but the PTO again rejected it, as well as prosecution claims 2 and 5-6, based upon prior art and a lack of enablement. Pet. App. 3a-4a; 36-37a. Mycogen re-filed its patent application, added new prosecution claim 31, and changed the dependency of prosecution claims 2-6 to new claim 31. Pet. App. 4a-5a. The Examiner again rejected prosecution claims 1-2, 5-6, and 31 as not enabled and as unpatentable over prior art. Pet. App. 5a.

Mycogen then canceled claim 31 and substituted prosecution claim 35, again changing the dependency of prosecution claims 2-6. Pet. App. 5a-6a. Claims 35, 2, and 5-6 were again rejected as not enabled and as unpatentable over prior art. Pet. App. 6a. Mycogen re-filed a second time. Pet. App. 7a-8a. Mycogen finally gave in and canceled all product claims that were not limited to the Figure 1 gene, stating that amendment "obviates the rejections which have been raised throughout the prosecution history of this application." Thus, the only product claims that Mycogen obtained in the '831 patent were limited to the exact sequence shown in Figure 1. Pet. App. 9a, 11a-12a.

REASONS FOR DENYING THE PETITION

Mycogen's petition is premised on the position that the so-called "complete bar" to the doctrine of equivalents arising from application of prosecution history estoppel under the Federal Circuit's decision in *Festo was* erroneously invoked against claims 13 and 14 by the Federal Circuit because those claims were never the subject of any narrowing amendment. Pet. at 5. However, Mycogen's petition merely attempts to further prolong Mycogen's baseless infringement assertions on claims 13 and 14 in light of this Court's decision to review the merits of the Federal Circuit's *Festo* decision.

The district court's summary judgment ruling that there could be no infringement of claims 13 and 14 under the doctrine of equivalents due to prosecution history estoppel was rendered in December 1995 -- almost five full years before the Federal Circuit's *Festo* decision. Mycogen's appeal to the Federal Circuit was fully briefed and argued before *Festo* issued. While the Federal Circuit cloaked its affirmance of the district court in the language of *Festo*, that decision did not create a new reason why Mycogen is legally unable to show infringement of claims 13 and 14 – it is because Mycogen clearly relinquished the claim scope necessary to cover Monsanto's accused gene when it canceled rejected claims that were too narrow to cover Monsanto in order to obtain the '831 patent. The rule that such a surrender of subject matter gives rise to an estoppel has been the law since long before *Festo*. *See Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-37 (1942) (and cases cited).

Claims 13 and 14, the only product claims in the '831 patent, were admitted by Mycogen during prosecution to be directed to the "exact" nucleotide sequence of the gene

disclosed in Figure 1 of the patent. Throughout six-plus years of prosecution before the PTO, Mycogen repeatedly attempted to obtain over 40 product claims of varying scope that were not limited to the exact sequence of Figure 1. The PTO repeated rejected all such claims on both prior art and nonenablement grounds. Eventually, Mycogen agreed to cancel all other product claims to obtain allowance of claims 13 and 14. Included among those canceled product claims were claims that were themselves too narrow to literally encompass the Monsanto gene accused of infringing those two product claims.

Based on those indisputable facts, the district court properly held under "pre-*Festo*" law that the only subject matter that Mycogen could have possibly recaptured by applying the doctrine of equivalents to claims 13 and 14 is that which falls between the scope of the rejected prosecution claims 2, 5 and 6 surrendered by Mycogen and the scope of the two product claims specific to the Figure 1 gene allowed by the PTO. Pet. App. 101a-102a. Because Monsanto's accused gene did not fall within Mycogen's potential range of recapture of claim coverage, there could be no infringement of the '831 product claims by Monsanto as a matter of law – even before *Festo*.

Correctly holding that prosecution history estoppel clearly attached in this case, the Federal Circuit *sua sponte* applied its *Festo* decision to hold that Mycogen could not recapture any genes beyond the literal scope of claims 13 and 14. Pet. App. 37a-38a; 2a-12a. However, the only practical significance of the decision to invoke *Festo* was that the Federal Circuit could decide that Mycogen was entitled to no range of equivalents at all before reaching the district court's equally-valid conclusion that any possible range of equivalents could not have been broad enough to encompass Monsanto's gene anyway. Either way, the inescapable legal

conclusion is that prosecution history estoppel bars any claim by Mycogen for alleged infringement of claims 13 and 14 under the doctrine of equivalents.

Regardless of whether this Court affirms, narrows, or reverses *Festo*, the doctrine of prosecution history estoppel as consistently applied by this Court and by every pre- and post-*Festo* decision of the Federal Circuit provides no basis for altering the conclusion that claims 13 and 14 cannot be infringed as a matter of law. Hence, this Court should reject Mycogen's suggestion that its petition must be granted and the case remanded to the Federal Circuit unless this Court affirms *Festo* entirely because the result in this case cannot possibly change in light of Mycogen's clear surrender of the very subject matter needed to encompass Monsanto's accused gene.

Finally, with respect to Mycogen's other question presented, the Federal Circuit's legal analysis and statutory construction of 35 U.S.C. § 271(g) is entirely correct, and thus presents no reason for this Court to review that aspect of the Court of Appeals' decision. Under the plain language of the statute, none of the commercial genes made using Monsanto's accused process before the '831 patent issued can infringe the '831 process claims under § 271(g) because those genes are not products "made by a process patented in the United States" as required by the statute. As properly interpreted by both lower courts in this case, §271(g) simply does not apply to create infringement liability for the use or sale of products made *before* a claimed process was later patented in the United States.

A. Mycogen Cannot Avoid Prosecution History Estoppel Simply Because Its Claims Limited To The Figure 1 Gene Were Not Narrowed

Mycogen's petition fails to acknowledge that every product claim that Mycogen introduced during prosecution that was broader than the "exact" gene in Figure 1 was rejected on prior art and enablement grounds, and each such claim was eventually canceled by Mycogen in order to allow claims 13 and 14 to issue in the '831 patent. Pet. App. 3a-12a. More importantly, several of Mycogen's rejected and later-canceled claims were too narrow to encompass Monsanto's accused gene – which is exactly why prosecution history estoppel has always prevented the doctrine of equivalents from being used to allow the asserted patent to encompass such surrendered subject matter.

Monsanto's position can be easily demonstrated by focusing on Mycogen's canceled prosecution claims 2, 5, and 6. Those cancellations -- at a minimum – properly foreclosed Mycogen from claiming a potential range of equivalents for prosecution claims 3 and 4 (issued as claims 13 and 14) which was outside the range falling between the canceled claims and the issued claims.

Mycogen's assertion that the cancellation of claims 2, 5, and 6 did not amount to a narrowing of the subject matter that could possibly be covered by the issued '831 product claims because those claims were not themselves amended or because claims 3 and 4 did not depend from claims 2, 5, and 6 is linguistic nonsense.[5] As the Federal Circuit correctly

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[5] The fact that Mycogen's two product claims were later rewritten in independent form does not alter the fact that each is limited to the gene shown in Figure 1 of the '831 patent. In any event, the amendment of those claims to independent form is not the basis on which the district court's or the Federal Circuit's estoppel decision was based. *See Mark I*

recognized, the cancellation of claims 2, 5, and 6 resulted in prosecution history estoppel affecting prosecution claims 3 and 4 just as if those claims had been directly amended to achieve their current form.

Using Mycogen's canceled prosecution claim 2 as a specific example, the Federal Circuit was correctly in stating that there is no substantive difference between (1) amending a rejected claim directed to a gene that is 85% homologous to the native gene so that it becomes limited to the specific gene shown in Figure 1 and (2) canceling a rejected claim directed to a gene that is 85% homologous to the native gene so that the only pending claim left in the application is limited to the specific gene shown in Figure 1. Pet. App. 37a-38a. As a matter of logic, there can be no difference for purposes of the rules announced in *Festo*. It should not matter for purposes of a patent owner's ultimate right to exclude whether the applicant begins by filing a set of progressively narrower claims and is only able to obtain the narrowest after canceling the rest in the face of PTO rejections, or whether the applicant begins with one broad claim and successively narrows it after a series of PTO rejections until its contents end up being the same as the narrowest one allowed in the former situation.

If Mycogen wanted to obtain additional coverage in the '831 patent beyond that signified by the claims directed

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Marketing Corp. v. R.R. Donnelly & Sons, 66 F.3d 285, 292 (Fed. Cir. 1995) (that particular claims were not themselves rejected or amended does not foreclose application of prosecution history estoppel). Moreover, the term "comprising" in the two issued product claims does not avoid the requirement that every specified nucleotide in Figure 1 must be present in any accused gene, regardless of what other elements may be present.

to exact gene in Figure 1, it could have either appealed the rejections or amended the rejected claims to a narrower scope (such as having at least about 95% homology with the native gene) and convinced the PTO that such narrower claim should be allowed. Of course, if Mycogen had done the latter, no further range of equivalents would be allowed under *Festo*. Having not done so, the Federal Circuit properly applied the rationale of *Festo* to limit Mycogen from using the doctrine of equivalents to recapture any subject matter beyond what is literally covered by the gene in Figure 1 because Mycogen elected not to seek it from the PTO before allowing the '831 patent to issue.

In that regard, *Festo* announced no new law nor altered any old law. In *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 30 (1997), this Court recently described prosecution history estoppel as being "a well-established limit on nonliteral infringement." Moreover, this Court explained that prosecution history estoppel most clearly arose when an applicant overcame a PTO rejection based on prior art by narrowing the scope of the original claim and effectively disavowing coverage of subject matter excluded by the amendment. *Id.* at 31 (citing *Exhibit Supply*, 315 U.S. at 136, and *Keystone Driller Co. v. Northwest Engineering Corp.*, 294 U.S. 42, 48 & n.5 (1935)); *see also* 520 U.S. at 31 n.5 (and other cases cited).

Long before *Festo*, the Federal Circuit also had consistently held that the doctrine of equivalents was not to be used as a tool for expanding the protection of a patent after the examination has been completed.

> An applicant should not be able deliberately to narrow the scope of examination to avoid during prosecution scrutiny by the PTO of subject matter with the objective of more

> quickly obtaining a patent (or avoiding the risk of an estoppel), and then obtain in court, either literally or under the doctrine of equivalents, a scope of protection which encompasses that subject matter.

Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1564 (Fed. Cir. 1994); *see Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 951-52 (Fed. Cir. 1993) ("The essence of prosecution history estoppel is that a patentee should not be able to obtain, through the doctrine of equivalents, coverage of subject matter that was relinquished during prosecution to procure issuance of the patent").[6]

The focus of a prosecution history estoppel analysis is on what subject matter was surrendered, not on how the claims may have been numbered before their cancellation. Given the clear substantive overlap between the subject matter of Mycogen's original application claims 3 and 4 and canceled claims 2, 5, and 6, Mycogen's suggestion that the Federal Circuit and the district court erred in relying on the relationship between the subject matter of those claims absent direct dependency between them can only be rejected. Thus, given Mycogen's demonstrated inability to get any other product claims allowed over the prior art coupled with Mycogen's express surrender of rejected product claims that were already too narrow to encompass Monsanto's accused

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[6] *See also Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 868 (Fed. Cir. 1993) ("A patent attorney should not be able, however, to choose one course of action within the PTO with the anticipation that, if later checked, he or she can always choose an alternative course of prosecution in a trial before a federal judge."); *Lemelson v. General Mills, Inc.*, 968 F.2d 1202, 1208 (Fed. Cir. 1992) (a patentee "cannot acquiesce to a rejection and to an agreed alternative, and now ... shift his stance 180° to argue for a second bite at the abandoned apple").

gene, the basis for prosecution history estoppel in this case is unmistakable under either pre- or post-*Festo* law.

The Federal Circuit properly held that Mycogen's contrary arguments indeed were placing form over substance. *See* Pet. App. 38a. The same is true of Mycogen's attack on the Federal Circuit's application of *Festo*. Mycogen's petition is directed more toward theoretical problems with *Festo* than on the Federal Circuit's application of *Festo*'s rationale to the present facts. *See* Pet. 20-21 (complaining that a "copyist" might be able to avoid infringing a gene claim by changing a single nucleotide, but then conceding that Monsanto's accused gene in this case had more than a one-nucleotide difference). As noted above, Monsanto's gene contains about 22% changes from the native gene, which is both outside the preferred range set forth in the patent as well as outside the range specified in proposed product claims rejected over prior art that were later canceled by Mycogen during prosecution.

Festo did not alter the prior precedent of this Court and of the Federal Circuit mandating the legal effect of relinquishing subject matter during prosecution, which was correctly followed by the district court in rendering its judgment of noninfringement. While Mycogen apparently assumes that this case must be remanded to the Federal Circuit if *Festo* is reversed or at all modified, Pet. 17, it is respectfully submitted that such a remand would be a waste of judicial resources. Whether evaluated under *Festo* itself or under "pre-*Festo*" law, Mycogen unambiguously surrendered the claim scope that would be needed to enable Mycogen to encompass Monsanto's accused gene under the doctrine of equivalents.

By cutting off a patentee's ability to recapture subject matter surrendered, the doctrine of prosecution history

estoppel thereby avoids making a court to indulge in speculative inquiry as to whether the patentee actually gave up too much. *Exhibit Supply*, 315 U.S. at 136 *see Wang Labs*, 993 F.2d at 868 (estoppel applies even though the patentee could have chosen a different or narrower basis for distinguishing the prior art cited by the PTO). Under *Festo*, there is no need to determine what was in fact surrendered because no range of equivalents is allowed once claim scope has been narrowed. 234 F.3d at 569-78. However, whether or not that absolute rule from *Festo* is retained, Mycogen cannot be allowed to use the doctrine of equivalents to inflate the exceedingly narrow product claims of the '831 patent to a scope previously relinquished.

A reasonable competitor reading the prosecution history of the '831 patent must be entitled to rely upon Mycogen's surrender of product claims that are too narrow to encompass such competitor's product. *Zenith Labs., Inc. v. Bristol-Meyers Squibb Co.*, 19 F.3d 1418, 1424 (Fed. Cir. 1994. Here, Mycogen canceled all such product claims -- after they had been rejected by the Patent Office for both prior art and enablement reasons -- in order to allow the '831 patent to issue. On that basis alone, prosecution history estoppel clearly must bar any possible infringement of claims 13 and 14 under the doctrine of equivalents in this case – as a matter of law.

Finally, Mycogen's alternative argument (Pet. 21-24) as to why this Court should still grant certiorari in this case even if this Court affirms the Federal Circuit's decision in *Festo* should be rejected. That makes no sense. If the narrowest claim in the application is made dependent upon a series of broader claims that are repeated rejected over prior art, the applicant cannot be allowed to avoid the resulting prosecution history estoppel limitation on the doctrine of equivalents by acquiescing in the rejections, canceling all

broader claims, and then asserting that the narrowest claim is infringed under the doctrine of equivalents by something that clearly falls outside the scope of the proposed application claims that were rejected and canceled.

Under Mycogen's apparent theory, a patentee can avoid be foreclosed in any manner by prosecution history estoppel as long as the original application contains the narrowest possible patentable claim that can be allowed without amendment, even if all other broader claims are continually rejected and never allowed. That turns the traditional doctrine of prosecution history estoppel completely on its head, and exposes Mycogen's petition as nothing more than an attempt to exploit any uncertainty over the Federal Circuit's *Festo* decision. If anything is certain about that decision, it clearly expanded the circumstances allowing prosecution history estoppel to bar reliance on the doctrine of equivalents. If Mycogen could not prevail as a matter of law before *Festo* was announced (as the district court correctly held), then Mycogen has no basis on which it could possibly prevail should *Festo* be affirmed.

For the reasons set forth above, this Court should deny certiorari in this case regardless of the outcome of its review of *Festo*. Indeed, unless this Court were to overrule its own precedents in *Warner-Jenkinson* and *Exhibit Supply* by abolishing the doctrine of prosecution history estoppel entirely (an issue not presented by *Festo*), Mycogen's petition can and should be denied before this Court even issues its *Festo* decision because nothing in either the Federal Circuit's *Festo* decision or rationale created a new basis for applying prosecution history estoppel in this case that did not exist under pre-*Festo* law.

B. The Federal Circuit's Interpretation Of 35 U.S.C. § 271(g) Was Completely Correct

It is undisputed that Monsanto's accused insect-resistant genes were designed and made before the '831 patent issued in 1995. Pet. 6 n.2. Nevertheless, Mycogen asserted that Monsanto's post-issuance use, sale, or offer for sale of products containing Monsanto's genes – genes that were made using what was at that time an unpatented process – infringes those process claims under 35 U.S.C. § 271(g). As the district court recognized when rejecting Mycogen's statutory interpretation (four times), and as properly affirmed by the Federal Circuit, Mycogen's position is at odds with the plain language and purpose of § 271(g).

"The starting point of every case involving the construction of a statute is the language itself." *Landreth Timber Co. v. Landreth*, 471 U.S. 681, 683 (1985). Section 271(g) states:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States, a product which *is made by a process patented in the United States* shall be liable as an infringer, *if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.* (emphases added.)

Thus, the determinative issue is whether a product of a process allegedly covered by the '831 process claims must have been made at a time when the process was actually "a process patented in the United States" (*i.e.*, after the U.S. patent covering the process issued). Monsanto's position is straightforward: before the '831 process claims issued, the Monsanto genes were made by a process *not* patented in the United States, so § 271(g) cannot and does not impose any

infringement liability for subsequent acts involving such products, whether during the term of the later-issued process patent or not.

Mycogen's interpretation below was based on the false premise that the last phrase of § 271(g) contains the only requirement for liability. According to Mycogen, because "making" is not a listed act, Congress did not require the act of manufacture using the patented process to take place during the patent term. Contrary to Mycogen's premise, however, "when" a process is used has a great impact on liability under § 271(g).

A court must read the statute as a whole. *United States v. Mortons*, 467 U.S. 822, 828 (1984). When read as a whole, § 271(g) imposes three distinct conditions for infringement liability. First, a product must be "made by a process patented in the United States." Second, the product must be imported into, offered for sale, sold or used in the United States (which was assumed here). Third, those acts must take place during the term of the process patent in question. Mycogen ignores the first condition, and misconstrues the third.

The past tense terms "made" and "patented" in the clause "made by a process patented in the United States" confirms that Congress intended it to have temporal significance in that the process being protected already be the subject of an issued U.S. patent. *See Gwaltney v. Chesapeake Bay Foundation*, 484 U.S. 49, 57-63 & n.4 (1987) (tense used in a statute is significant). By giving meaning to all the phrases, not just the last one isolated by Mycogen, the Federal Circuit and the district court correctly held that no liability can attach to Monsanto's products made before the process was patented in the United States because

the process used was not "patented" when the product was "made." Pet. App. 34-35a.

Despite its mischaracterization of *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996), being expressly rejected by the very court that authored the opinion, Pet. App. 33a, Mycogen continues to assert that a conflict exists between that decision and this one. However, *Bio-Technology* does not support Mycogen's attempt to ignore the express statutory language of § 271(g). There, Genentech sought to enjoin importation of an artificial hormone produced using a process covered by two U.S. patents. One covered a process for constructing a plasmid, which, when introduced into a microbial organism, caused the hormone to be produced. 80 F.3d at 1557. Bio-Technology constructed the plasmid once, in Israel, in 1983. Notably, Genentech's patent issued in 1982, before § 271(g) was effective. 80 F.3d at 1562.

Bio-Technology argued that it was improper to apply § 271(g) retroactively to conduct that was not an infringement at the time. 80 F.3d at 1562. The Federal Circuit disagreed, holding that the infringement "does not consist of the making of a product patented in the United States; it is the importation, offer to sell, sale, or use of a product made by such process that infringes." *Id.* Actually, however, liability under § 271(g) requires all three statutory conditions described above to be met, which was clearly the situation in *Bio-Technology*.

Mycogen's attempt to forcefit *Bio-Technology* to this case misses a critical distinction. In *Bio-Technology*, the process used in 1983 to construct the plasmid was "patented in the United States" at that time. Even though § 271(g) was not effective, this Court held that the subsequent importation of a product "made by such process" during the term of the

patent came within § 271(g). 80 F.3d at 1560. However, that ruling cannot extend Mycogen's process patent rights to the period before its process was patented. Unlike in *Bio-Technology*, Mycogen had no United States process patent to enforce at the time of Monsanto's use. Thus, Mycogen cannot invoke § 271(g) now.

Mycogen's interpretation would revise § 271(g) to encompass products made by a process which "subsequently" or "eventually" becomes "patented in the United States." As the Federal Circuit held, nothing in § 271(g) altered the fundamental rule that a U.S. patent can only be infringed during the term of the patent. Pet. App. 35a; *see In re Amtorg Trading Corp.*, 75 F.2d 826, 831-32 (C.C.P.A. 1935). Section 271(g) merely provides a remedy for acts that would have been infringements of a U.S. process patent but for the fact that the process was being performed outside the United States. *See* S. Rep. No. 83, 100th Cong., 1st Sess. 46 (1987). However, completion of a process before a patent issued on that process has never been an act of infringement, no matter where it was performed. That rule was not altered by § 271(g).

Mycogen's attempt to impose liability for the completion of a process before a United States patent issues on that process is also wholly inconsistent with the statute's legislative intent. The dominant purpose underlying § 271(g) was to prevent manufacturers from having the unfettered ability to copy a process from an issued U.S. patent, to use that process in another country to make unpatented products, and then import, use, or sell those products in the United States in competition with the U.S. process patent holder. *E.g.*, H.R. Rep. No. 807, 96th Cong., 2d Sess. 19 (1986)). The legislative history unmistakably reveals that Congress was acting to eliminate that loophole in U.S. law. *See* S. Rep. No. 388, 100th Cong., 2d Sess. 33 (1988) ("Current

patent [illegible] does not reach the foreign pirating of American innovations when the products are manufactured abroad and then shipped back to the United States."). Clearly, the problem being remedied, copying U.S. process patents for use overseas, could only arise after a U.S. patent had issued.

Early versions of the bills that ultimately resulted in § 271(g) limited the scope of the added protection to the importation, use or sale of products "made in another country" by such processes. Because the United States could not discriminate against foreign companies under its GATT obligations, all bills proposed after 1984 provided only that importation, use, and sale of products made by processes patented in the United States would be infringements; *i.e.*, regardless of where the products were made. *See* S. Rep. No. 663, 98th Cong., 2d Sess., sec. IV, at 5 (1984) (broader language adopted "to avoid any appearance of discrimination against foreign manufacturers"). However, Congress concluded that giving an infringement remedy with respect to the use or sale of a product made in the United States would have little practical significance because the patentee already had an existing remedy for process patent infringement directly against the domestic manufacturer. *See, e.g.*, S. Rep. No. 83, 100th Cong., 1st Sess., Sec. III, at 44 (1987).

A U.S. process patent owner did ***not*** have an existing remedy against use of a process in the United States ***before*** the patent issued. Nothing in the legislative history indicates that Congress intended or understood that it would be changing the law to allow infringement liability to attach to products made by practicing an unpatented process in the United States before the patent on that process issued. Such a significant change to U.S. law cannot be presumed to have been done by Congress unwittingly or in utter silence.

H.R. Conf. Rep. No. 576, 100th Cong., 2d Sess. 1086 (1988), stated that the House and Senate bills agree that "using, selling or importing a product *made in violation of a U.S. process patent* is an act of infringement." A6193 (emphasis added). *See RJR Nabisco, Inc. v. United States,* 955 F.2d 1457, 1462 (11th Cir. 1992) (a conference committee report is the legislative history accorded the greatest deference by courts). Because a patent cannot be "violated" before it issues, that report confirms that Congress contemplated that only post-issuance uses would be implicated by § 271(g).

Based on the above, the Federal Circuit concluded that the process claims 1-12 cannot be infringed by the Monsanto commercial *Bt* genes made before the '831 patent issued. There is no reason for this Court to undertake to review that entirely correct decision.

CONCLUSION

The petition for a writ of certiorari should be denied in its entirety.

Respectfully submitted.

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IN THE

Supreme Court of the United States

MYCOGEN PLANT SCIENCE, INC.
and AGRIGENETICS, INC.,

Petitioners,

v.

MONSANTO COMPANY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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STATEMENT PURSUANT TO RULE 29.6

Petitioners' corporate disclosure statements were set forth at page *ii* of the Petition for a Writ of Certiorari, and there are no amendments to those statements.

Petitioners Agrigenetics, Inc. and Mycogen Plant Science, Inc. (collectively, "Mycogen") submit this reply to Respondent Monsanto Company's ("Monsanto") Brief in Opposition to Mycogen's petition for a writ of *certiorari* (the "Petition") to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

REPLY TO MONSANTO'S REASONS FOR DENYING THE WRIT

1. Certiorari Should Be Granted For Question One Set Forth In Mycogen's Petition Because Any Modification Of *Festo* By This Court Combined With A Denial Of Mycogen's Petition For Question One Would Result In Unequal Treatment For Mycogen.

Question One in Mycogen's Petition invites this Court to employ the procedure of granting certiorari, vacating the judgment below and remanding the case (commonly referred to as "GVR") to the Federal Circuit to allow it to decide the issue of prosecution history estoppel in light of whatever decision this Court may render in *Festo Corporation v. Shotketsu Kinzoku Kogyo Kabushiki Co.*, No. 00-1543, argued January 8, 2002. *See* Petition at 17-18. This Court has GVR'd cases in response to developments in the law, including its own decisions. *See Lawrence v. Chater*, 516 U.S. 163, 166 (1996). This practice has a number of virtues, chief among them in this case that it "alleviates the '[p]otential for unequal treatment' that is inherent in [the Court's] inability to grant plenary review of all pending cases raising similar issues." 516 U.S. at 167. A GVR order is appropriate when:

> [I]ntervening developments, or recent developments that we have reason to believe the court below did not fully consider, reveal a reasonable probability

> that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration, and where it appears that such a redetermination may determine the ultimate outcome of the litigation.

516 U.S. at 167.

Mycogen has property rights in claims 13 and 14 of U.S. Patent No. 5,380,831 ("the '831 patent"). The Federal Circuit woodenly applied the absolute bar to equivalents set forth in its decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000) (*en banc*), to claims 13 and 14, denying Mycogen any effective claim scope other than the literal nucleotide sequences recited therein. This decision, resting entirely on *Festo*, deprives Mycogen of its property. If this Court resolves its hearing of *Festo* with any rule other than a blanket affirmance of the "absolute bar," the *Festo* issue that is the subject of Mycogen's Petition would then rest entirely on a discarded premise. The proper course would be a remand to the Federal Circuit to allow that court to consider and analyze the parties' arguments free from the "absolute bar."

Monsanto, attempting to avoid a remand in which any decision by this Court in *Festo* could be addressed, ignores the fact that the Federal Circuit relied solely on *Festo* in affirming the district court, and re-argues its original position based on pre-*Festo* law. The Federal Circuit's use of *Festo* to avoid the arguments and analysis the parties presented, however, is what makes the GVR procedure wholly appropriate here. Plainly, the Federal Circuit's opinion does not reflect consideration of the parties' pre-*Festo* arguments concerning the doctrine of equivalents. That court dispensed with those arguments and instead relied on the *en banc Festo* decision — decided after briefing and oral argument in this case — to uphold the district court judgment on equivalents. *See Mycogen*, 234 F.3d at 1319-20 and 261 F.3d at 1349-50.

If this Court's disposition in *Festo* either restores the pre-*Festo* flexible bar regarding the doctrine of equivalents or announces a new rule that is different from both the pre-*Festo* flexible bar and the Federal Circuit's absolute bar, Mycogen is entitled to have the limits of its property rights in claims 13 and 14 of the '831 patent evaluated under the correct rule of law. Accordingly, this case meets the standards for GVR and this Court should use that procedure if its *Festo* decision in any way alters the absolute bar rule of the Federal Circuit's *en banc* opinion.

2. Monsanto's Prosecution History Estoppel Arguments Are Incorrect As A Matter Of Pre-*Festo* Law

Monsanto's prosecution history estoppel arguments are incorrect as a matter of pre-*Festo* law. Mycogen will not describe all of the deficiencies in Monsanto's arguments, as that is not appropriate in the context of a *certiorari* petition, and this Court should not in any case be addressing the merits of the prosecution history estoppel argument under pre-*Festo* authority now. That task, if made necessary by a reversal or modification of *Festo*, should be undertaken first by the Federal Circuit. However, Mycogen will respond to one of Monsanto's more egregious arguments, to demonstrate that a GVR is not futile but, instead, would return the case to the Federal Circuit for a redetermination that would directly impact Mycogen's claims of infringement of claims 13 and 14 of the '831 patent.

Contrary to Monsanto's unwarranted disparagement of Mycogen's argument as "linguistic nonsense," (Opposition at 16), it is actually Monsanto's position that is devoid of logic. Monsanto argues that, under pre-*Festo* law, Mycogen surrendered subject matter by canceling claims 2, 5 and 6, notwithstanding that claims 3 and 4 (which issued as claims 13 and 14) remained pending and depended from an independent claim that *was broader in scope* than any of

cancelled claims 2, 5 and 6. Because a prosecution history estoppel argument properly examines the scope of what subject matter was surrendered, Monsanto's position that Mycogen could somehow surrender narrow subject matter while retaining claims *broader in scope* than the purportedly surrendered subject matter is logically absurd. Whatever Mycogen may have surrendered is governed, at the outer boundaries, by the scope of the broad independent claims, not by the scope of cancelled intermediate claims that were narrower in scope than the independent claims that remained pending in the application.

Mycogen's later cancellation of these broader independent claims does not change this analysis, as Mycogen continued to pursue them in a continuation application, a course of action implicitly sanctioned by the Federal Circuit as a means for avoiding imposition of prosecution history estoppel under pre-*Festo* law. *Haynes Int'l., Inc. v. Jessop Steel Co.*, 8 F.3d 1573 (Fed. Cir. 1993), *amended by*, 15 F.3d 1076 (Fed. Cir. 1994). In *Haynes*, the patentee cancelled two broad claims and re-wrote dependent claim 5 as an independent claim when the Board of Patent Appeals and Interferences concluded that claim 5 was patentable, but claims 1 and 4 were not. 8 F.3d at 1577. In considering the application of prosecution history estoppel, the Federal Circuit concluded that prosecution history estoppel arose from the *combination* of cancellation of the broad claims *plus* the patentee's failure to refile a continuation application to pursue issuance of the broader claims. 8 F.3d at 1578. Indeed, the Federal Circuit observed "the cancellation of the claims did not establish that Cabot [the patentee] wanted to relinquish coverage of the subject matter encompassed by them and thus did not necessarily create an estoppel." *Id.*

In contrast to the patentee in *Haynes*, Mycogen pursued the broader claims in a continuation application, a fact that was recognized by the district court. The district court erred

when it concluded nevertheless that further pursuit of such broader claims was irrelevant. To the contrary, Mycogen followed the very path sanctioned by the Federal Circuit to avoid blanket application of the estoppel by permitting allowable claims to issue and pursuing broader claims in a continuation application. Thus, under the pre-*Festo* rules of prosecution history estoppel, the scope of claims 2, 5 and 6 should have no bearing on Mycogen's ability to assert infringement under the doctrine of equivalents.

3. The Court Should Grant Certiorari To Correct The Federal Circuit's Erroneous Interpretation Of 35 U.S.C. § 271(g)

Mycogen rests on its Petition as a sufficient argument of the reasons to grant certiorari on the third question presented. *See* Petition at 24-29.

CONCLUSION

Mycogen's petition for a writ of certiorari should be granted.

Respectfully submitted,

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